

Cervical Cap

Background

The cervical cap is one of the oldest forms of female controlled contraception. The original device was a half a lemon then there were metal and then latex cups that fit over the cervix. The FDA approved the latex Prentif cervical cap years ago, it must be fitted by an exam, it comes in 4 sizes, and requires a spermicide for efficacy. As of 2005 the company decided to no longer sell the Prentif cap in the United States. There is now a silicone cap, the FemCap, which comes in 3 sizes determined by reproductive history (22mm=nulligravid, 26mm=nullipara, 30mm=parous). The spermicide is placed in the cup portion of the cap facing the cervical os and in an external groove of the cap. The typical user failure rate is 20-40% in nulliparous compared to parous women in the first year of use (perfect user rates are 9-26% respectively). These rates are higher than the diaphragm rates of 6-20% for perfect-typical failure rates.

Contraindications and Precautions

- When placement is prohibited by variations of anatomy limiting fit or conditions that hamper reaching into the vagina, such as thick abdominal fat, short fingers, or a deep vagina;
- Psychological obstacles such as a client's reluctance in touching her own genitals, unless her partner wishes to insert device. The partner must come in to clinic to learn proper insertion;
- An inability to learn the proper method of insertion;
- Recurrent urinary tract infections. Advise women to drink ample fluids;
- History of toxic shock or vaginal Staphylococcus;
- Allergy to rubber (latex) for Prentif cap use;
- Allergy to spermicide. Advise women to try a change of spermicide and if problems persist, to change contraceptive method;
- Intractable yeast infections or bacterial vaginosis;
- Cervicitis or unresolved PID;
- Delivery within last six weeks;
- PAROUS WOMEN especially if vaginal delivery, have a much higher failure rate due to the change in cervical size and poor fit of the cervical cap. Nulliparous women have a first year perfect use failure rate of about 9% while parous women have a failure rate of 26%. The diaphragm failure rate is not increased with parity as long as the size of the device is fitted properly.

Benefits

- Little interference with sex;
- Better sensation than diaphragm;
- More comfortable than diaphragm;
- Some protection from STD.

Prescription of Cap

This method is not available on site. Clients requesting a cervical cap may be given appropriate education and then referred to purchase the FemCap directly from the website or the prescription can then be sent to the Downtown PHSKC Pharmacy and they will then order the cap for the client. Each cap costs approximately 60 dollars.

Initial Clinic Visit

The standard medical history is reviewed and enlarged upon as clinically appropriate by the clinician. The minimum required physical examination is performed and recorded, and if needed, additional examination done as indicated by the history. Minimum laboratory tests are obtained and reviewed. Where disease is diagnosed or suspected on the basis of any of the above, referral will be made either to the clinic physician or other care provider as appropriate. Inform the client about emergency contraception and for many clients it is appropriate to prescribe and dispense a package of EC for use if method failure such as non-use or slippage. It is even reasonable to consider recommending the client use a male condom with ECP in the first few months of learning how to use the cervical cap.

Subsequent Clinic Visits

The woman should return if she has problems or as needed for supplies. A cytology test and exam should be done yearly.

Possible Side Effects

- **Increased vaginal discharge complaints:** Examine for yeast, bacterial vaginosis, etc. If problems persists, the client may need to change to a non-barrier method.
- Pain or injury in either partner from contact with the FemCap device.

Patient Method Education

- Use the device prior to genital contact.
- Have annual fitting checks especially if weight changes or pregnancy.
- Replace the device if latex is brittle, cracked, or every 2 years if FemCap device.
- Place a teaspoon of spermicidal jelly in the center of cap facing the cervical os and in the external groove of the FemCap prior to use.
- May apply the device up to 6 hours or just prior to intercourse.
- Leave the device in place for a minimum of 6 hours after intercourse and a maximum of 48 hours.
- Wash the device in mild soap and water, store in a cool dry place without powders.
- Oil-based lubricants and medications will damage the latex Prentif and deteriorate the cap. The FemCap should also be replaced every two years but is not latex.

C

ondoms - Female

Description

The female condom, which goes by the brand name Reality, is made of a vinyl tube with 2 rings. One ring fits outside the vulva and the other ring helps to hold the vinyl tube in the vagina. The failure rate with the first year of use is 5 to 25% and although it has been shown to decrease trichomonas reinfection, it is not as effective as the male condom in preventing STDs or pregnancy. Breakage is very rare but slippage with semen exposure is more common at 7–21%.

Contraindications and Precautions

- Inability to learn correct insertion technique;
- Anatomical abnormalities that interfere with proper placement or retention such as pelvic relaxation, vaginal septum, large vagina, etc;
- Allergy to the vinyl device or the silicon lubricant;
- Is less effective than male condoms with a failure rate 5-25% during the first year.
- There was more semen exposure with the female condom with a large disparity between penis and vaginal size and with very active intercourse (*Am J Epidemiology 2003: 157: 282-302*).

Benefits

- Contraceptive protection;
- Some protection against STDs;
- Available without prescription;
- Women can initiate method.

Possible Side Effects

- **Allergy to vinyl** may occur in either partner: Allergy is uncommon. Change contraceptive method;
- **Displacement:** condom may be pushed inside the vagina or pushed aside by the penis. If this occurs client should consider emergency postcoital contraception (EC);
- **Discomfort** due to the external ring, there is only one size so this cannot be helped;
- **Noise or discomfort:** use more lubricant.

Dispensing

This method may be available on site, but due to cost, only three should be dispensed at a time. Many women may decide not to use them or switch to the more effective male condom.

- Female condoms are available without a prescription over the counter. Medicaid will cover the cost if the client is given a prescription to fill at outside pharmacies.
- If the woman brings a condom, then clinic examination and demonstration may facilitate learning to place the condom. The woman observes her cervix with a mirror and palpates her cervix while in the clinic. Review instructions for placement and removal of the condom.
- EC should be supplied as a back-up. This is especially important given the high failure rate.

C

ondoms - Male

Benefits

- Good contraceptive protection if used consistently.
- Good protection against STD. Protection is best with latex or vinyl condoms as natural skin condoms have pores large enough for viral particles.
- Lower incidence of abnormal Pap smears.
- Treat premature ejaculation
- Decrease antisperm antibodies
- Available without prescription at low cost.

Contraindications and Precautions

- Inability to maintain an erection when a condom is used
- Allergy to rubber (latex). There are vinyl condoms but they can have a 10% breakage rate for some men and in a randomized trial had more failures (Obstet Gynecol 2003; 101:539-47). Therefore, these condoms should be used only with latex allergies or individuals accepting a higher failure rate.
- Oil based lubricants and medications can cause rapid deterioration of latex condoms and subsequent failure. Avoid oils, grease, ointments, hand lotion, petroleum jelly, rubbing alcohol, and medications containing these substances. Vinyl condoms like the female condom are not latex and can be used with oil-based lubricants.
- Reduced sensitivity for either partner. Use of water-soluble lubricant or spermicide inside tip of condom and in vagina may help enhance sensitivity. Vinyl condoms (Avanti) have been reported to be preferred with greater sensation, however, the breakage and slippage hence failure rates are higher.
 - Interruption of foreplay to apply. Partner may help apply the condom.
 - Can not use with female vinyl condom because this can cause the male latex condom to break. Male vinyl and skin condoms have not been studied when used with female condom.

Possible Side Effects (May occur in either partner)

- **Allergy to spermicide or lubricant:** Try condoms without spermicide or lubricant. If symptoms improve try lubricated condoms without nonoxynol-9.
- **Allergy to latex:** Allergy to latex is common. Use non-latex condoms like vinyl or natural skin condoms or change contraceptive method.
- **Breakage:** May be due to incorrect application trapping air or without a space to collect semen. Frequently occurs from improper storage or use of oil based substances which cause deterioration. Care must be taken with sharp objects or fingernails. Review proper use. Suggest a stronger condom if appropriate. Studies with vinyl condoms found that they were more likely to “pop” as they had less ability to stretch. Therefore, a larger size should be used if possible. In Europe there is a “baggy” condom with a vinyl bag and elasticized base.

Dispensing

- Offer condoms to all clients as an interim, supplemental or backup method of contraception.
- Offer condoms to **ALL** persons (male and female) for protection against STD unless they state they are in a mutually monogamous relationship.
- All clients with a STD should be given condoms both for protection during treatment and to prevent future infection.
- Provide handouts on the use and application of condoms whenever they are dispensed.
- Placing condoms in a basket on the counter or in high, but obviously visible, containers in both women's and men's rest rooms is encouraged.
- Make condoms available without necessity for examination or filling out clinic forms. However, if an encounter form is generated, list the condoms as a contraceptive method so the program can get credit for the dispensing of the condoms, but do not bill as a pharmacy item for the condoms because they were not dispensed as a pharmacy item.
- The male vinyl condom and the female condom are specific items and should be dispensed from the pharmacy, billed for separately using the encounter form, and not left in baskets as they require additional counseling and cost.
- Inform the client about emergency postcoital contraception (EC). For most clients it may be appropriate to give EC prescriptions prophylactically and this should be encouraged.
- Using a condom is much safer than unprotected sex.
- Water based lubricants used with condoms can decrease the risk of the condom breaking.

Patient Method Education

- Condoms alone are 88% effective with typical use and 98% with perfect use. Almost all condom failures are due to non-use, breakage, or slippage, therefore the use of EC in these cases could increase efficacy of the method. It is strongly recommended that women using condoms for contraception be educated about EC and be provided a prescription of EC to use in the future if needed. (see Emergency Contraception chapter in Guidelines)
- If a woman insists she wants to use spermicidal foam in addition to the condom, she should insert the contraceptive foam 15 minutes prior to intercourse to allow dispersal of the chemical. The foam is there to help kill sperm if the condom breaks or slips off.
- (See Spermicide section of the guidelines.) Spermicidal chemicals, usually nonoxynol-9, or N9, when used in repeated or high doses can cause vaginal irritation and breaks in the vaginal epithelial barrier. This has been shown to increase the risk of transmission of blood borne diseases like HIV or Hepatitis. A single low dose use of ≤ 150 mg of N9 is probably safe, but the need to use N9 foam with a condom has never been proven to be more effective than a condom alone.
- The amount of N9 in a N9 impregnated condom is tiny and it is probably not sufficient to kill all the sperm in the ejaculate. This type of condom does not have a long shelf life and it has been associated with releasing the latex proteins and therefore could increase the risk of latex allergy. Therefore, these condoms are not recommended for vaginal or rectal use. The rectal mucosa is especially vulnerable to the N9 chemical damage and N9 should never be used in the rectum.
- Apply condom prior to genital contact.
- If lubricant is used, it can be put on the glans of the penis prior to putting on the condom – it can improve penile sensation and pleasure.

- Pinch the tip of the condom so that an inch of deflated condom is at the top of the glans making room for the ejaculate.
- After ejaculation, withdraw the penis prior to becoming flaccid and hold the base of the penis to keep the condom from slipping off and leaving ejaculate near vagina or vulva.
- Dispose of the condom properly.
- Use a new condom with each act of intercourse.
- Withdrawal or coitus interruptus can also be practiced if condoms are not available. It involves male ejaculation outside the vagina. If a man has urinated prior to intercourse this can reduce the number of viable sperm in the urethra and ejaculation is external, away from the entire genital area, there can be some reduction in exposure (better than nothing). However, the pre ejaculate fluids can still contain infectious agents and this method is inferior to traditional barrier methods.

D

epo Medroxyprogesterone Acetate (Depo-Provera) or DMPA

Overview

Depo provera is a microcrystalline suspension of medroxyprogesterone acetate (DMPA), a first generation progestin. It has been available around the world as a contraceptive for 30 years. It is slowly released and reaches therapeutic levels (average 3.5 ng/mL) in 3-7 days. It is very effective with a failure rate of 3 pregnancies in 1000 women using DMPA in the first year when given every 12 weeks. DMPA blocks ovulation unless the serum levels drop below 0.1 ng/ml, thickens cervical mucus, and atrophies the endometrium. Serum levels can persist up to 9 months. Because DMPA induces ovarian suppression there is often only a very low level of natural estradiol production (levels less than 30 pg/mL are common) and therefore it is similar to the levels of estrogen experienced by women during lactation and menopause.

Absolute Contraindications

For women with any of the following, DMPA **should not** be injected:

- **Allergy** to Lunelle or Depo provera in the past. There are chemicals in the injection preparation (preservatives/vehicle) which can trigger allergic reactions including anaphylaxis (very rare) and dermatologic (rash, itch).
- **Known pregnancy**, although there is no evidence of teratogenesis in women who inadvertently receive DMPA early in pregnancy they may delay entry into prenatal care because they do not recognize the pregnancy.
- Known or suspected **breast or uterine cancer**.
- **Use of aminoglutethimide (Cytadren)**: This drug used rarely to treat adrenal tumors or Cushing's disease interrupts the synthesis of cortisol, aldosterone, and estrogen by inhibiting cholesterol conversion. The drug induces metabolism of the DMPA, which may reduce the bioavailability of the DMPA, hence decrease effectiveness.
- Any condition that could worsen with **increased cerebral fluid** in the **brain** like a meningioma, brain tumor, or pseudotumor cerebri.
- **Osteoporosis, osteopenia, or condition known to induce bone loss** such as chronic oral steroid use, prior stress fracture, hereditary bone or collagen or malabsorption disorders. These women should not get long-term DMPA without consultation and management with primary care including imaging to assess bone density.

Relative Contraindications

Women with the following **may be given** DMPA if an alternative method of contraception would not be acceptable to the client or would increase the risk of an unwanted pregnancy.

- **Plans for pregnancy within one year**: Client must understand that they may have amenorrhea, irregular menses, and may be unable to get pregnant for 12-18 months after the last shot was given. No infertility workup is indicated until 18 months from the last DMPA injection. If the woman is age 33 or older and plans a pregnancy soon, she needs to sign the [Birth Control Method Specific Informed Consent Form](#) to document she was warned the use of DMPA may greatly decrease her fertility.
- **Inability to tolerate irregular, frequent bleeding**: Client must be aware that irregular bleeding is common and expected during the first 6 to 12 months of DMPA usage.
- **Inability to tolerate amenorrhea**: Client must be aware that amenorrhea is to be expected

after using DMPA for 12 months in 50% of women and 80% by 2 years of use.

- **Known HDL cholesterol <40 and family history of CAD** (1st degree male relative with MI or stroke before age 55 or female relative before age 65.). Obtain lipid panel prior to first or second injection, if results are normal, the clinician may continue to prescribe DMPA. Repeat the lipids in one year to make sure lipids continue to be normal. If abnormal (specifically HDL <40 or LDL >180) then advise no DMPA unless she signs the [Birth Control Method Specific Informed Consent Form](#), as DMPA use may worsen her lipid profile and could lead to coronary artery disease.
- Women with **seeking more than 2 consecutive years of DMPA use** (see [Bone Health Guidelines](#)). We know women experience a low estrogen state with DMPA use and this can decrease their bone density. The bone loss is reversible just like during lactation and it is common for bone density to decrease by 6 to 7% similar to menopause. It is unknown if prolonged use of DMPA in the adolescent years will impact peak bone density acquisition. A small cohort study followed former DMPA users into their menopause years and found these women had already lost their estrogen sensitive bone component and they did not experience additional bone loss at menopause and these women using HRT responded with an increase in bone density (Cundy T. et al. Menopausal bone loss in long term DMPA users. Am J Obstet. Gynecology 2002; 186: 978-83). The 2001 WHO Medical Eligibility Criteria for Contraceptives recommends caution in prescribing DMPA for **women aged <18 or >45** because of these concerns. At the time of initiating use of DMPA for these clients, the [Birth Control Method Specific Informed Consent Form](#) is to be signed to document the woman is aware of the low estrogen and bone effects while using DMPA and still chooses DMPA over other methods. In addition all PHSKC clients getting their 8th or more continuous DMPA injection should also sign this informed consent form annually. The [Bone Health/Calcium/ Osteoporosis Handout](#) can also be given although it is unlikely calcium or exercise can completely reverse the effects of long-term hypo-estrogenism.
- **Undiagnosed abnormal vaginal bleeding.**
- **Severe depression** but if stable and on medication, she could try a trial of oral Provera (medroxy progesterone acetate) 30 mg (likely more than a contraceptive dose and 10 mg may be enough but unstudied, so prudent to use more than 10mg a day), every day for 30 days. If mood or depression is not worsened, the client could consider DMPA.
- **Women 50 or older** should usually not be prescribed DMPA unless bone density, lipid testing, menopause screening, and mammogram monitoring are addressed by their primary provider. These services currently are outside the scope of the family planning practice and would need to be coordinated and performed by the woman's primary provider. Because of the concerns regarding bone density it is usually not in the woman's best interest to continue DMPA after 50 although if this is the only method she can use, for example has thrombotic risk factors for the OC, then it is reasonable to provide the DMPA rather than risk a pregnancy providing documentation of the counseling and decision making is performed.

Benefits

- Highly effective
- Easy compliance
- Long-acting - only one injection every twelve weeks
- Decreased PMS, ovulatory pain, menstrual flow, cramps, and anemia
- Decreased PID due to thickened cervical mucus and atrophic endometrium
- Treats endometriosis
- Decreased endometrial and ovarian cancer
- No adverse effects on nursing and many promote breast milk production

- No interference with epilepsy medication serum levels, and because progesterone raises the seizure threshold, DMPA can actually decrease the number of seizures
- Proven to decrease painful crises in sickle-cell anemia patients

When to Administer

When beginning DMPA, it is best to administer the first dose within five days of the onset of menses or less than 7 days from abortion so the woman will be fully protected from the time of the injection. DMPA is not rapidly absorbed and will not act as an emergency contraceptive to block ovulation emergently.

Women not at risk for pregnancy may have an injection at any time of the month. For other women, the first injection should be during the first 5 days of the menstrual cycle and if not, the shot can be given that day only if a negative UCG test is documented and the same day start/restart protocol used which means the patient agrees to use a back-up method for 7 days, understands the possible risk of false negative HCG test if she has had unprotected sex in last 2 weeks, gets ECP if needed, and agrees to return for a four week follow-up pregnancy test or if no bleeding.

Women who have had unprotected sex, and if it has been less than 120 hours, may desire an ECP prescription. Advise additional caution if multiple acts of unprotected intercourse since her risk of an early pregnancy is increased and consider waiting till menses for DMPA administration. If the DMPA was administered and the woman is subsequently found to be pregnant and undergoes an abortion, the DMPA should be re-administered sooner (8 weeks or sooner) rather than the prescribed 12 week interval because it is not known if the pregnant metabolic state could hasten the metabolism of the DMPA.

Anyone worried about a possible pregnancy may choose to wait for menses to start their DMPA. Clients should use backup contraception for 7 days following the first injection if not given within 5 days of onset of menses, or if greater than 2 weeks from a delivery. Ovulation may have occurred and the DMPA is not an EC and it takes 7 days for the DMPA progestin effect on the cervical mucus to be established. Back-up contraception is only needed for 7 days from injection because although women can still ovulate within 3-4 days after injection, by 7 days the serum levels of DMPA will be adequate to both block ovulation and to change the cervical mucus to a barrier to sperm, (*Fertility and Sterility* 1998; 70: 817-20).

Postpartum, DMPA can be given the day after delivery at many institutions, however irregular bleeding may be less if it is begun 4-6 weeks postpartum. There is no reason to withhold DMPA if contraception is needed since ovulation can occur by 3 weeks postpartum in non-lactating women.

History and Examination

The standard medical history should include history of depression, obesity, vaginal bleeding, or breast concerns. The physical examination is performed and recorded to include weight, blood pressure, cervical, breast, and pelvic examination. If the delayed pelvic option is used, the pelvic must be done prior to the second injection or after 6 months of use or else they must sign the [Birth Control Method Specific Informed Consent Form](#) (see Delayed Pelvic section of the guidelines). The client should be educated about the risks and benefits of DMPA and alternate contraceptive methods. Complete the [Female Family Planning / STD Visit Form](#) for each following visit until the annual examination, which can be no sooner than 10 months from

the last annual exam. Clients should be assessed for their risk for low bone density if they have decided to use DMPA beyond 2 years of use. Risk factors for low bone density are discussed in the [Bone Health Guidelines](#).

Lab Tests

Pregnancy testing should be documented for most DMPA starts or restarts and often prior to the second injection if the first injection was a same day start/restart, and is mandated if there has been no vaginal bleeding since the initial shot. In long-term DMPA users with amenorrhea there is no need to repeatedly test for pregnancy unless there are missed shots or concerns. Remember even after years of DMPA use being more than a week late for a shot can still result in pregnancy. A hematocrit or hemoglobin may also be indicated if the client has been experiencing heavy bleeding.

Injection Technique

Give the client a copy of the patient product package insert to read BEFORE the injection and discuss the rare possibility of allergic reactions and advise her to wait in the clinic for 15-20 minutes following her injections if she chooses although this is not required by the package labeling. The risk of reaction is very small and it can happen even in prior or long-term users. In the early studies with DMPA used by 4200 women over 1 to 6 years, only 1.1% of women reported a rash, 0.4% reported allergic reactions (not otherwise specified), and 0.9% reported hives (Package insert). Providers administering DMPA need to follow the PHSKC clinic policies for allergic reaction and anaphylaxis including insuring there is epinephrine on site. It is recommended to inject the epinephrine into the DMPA injection site as well to slow the drug absorption. In cases of documented allergic reaction she should probably be sent to a hospital for additional observation in case there is a delayed reoccurrence or worsening of symptoms as she may need steroids or antihistamine treatment as well. As of 2004 a generic version of DMPA became available and it has the identical ingredients and amounts of these vehicles or preservatives (polyethylene glycol, polysorbate, sodium chloride, methylparaben, and propylparaben) as the brand product. However any manufacturing lot can vary and even the supplier can change so the potential for something that triggers an allergy is always possible with an injection.

The prescription can be indicated by DMPA checked on the chart note to read: "DMPA 150 mg IM injection every 12 weeks for one year" and this is duplicated on the medication list in the chart. The solution should be kept at room temperature and any heating of the solution is not recommended as it could change the solubility. The injection is prepared using a vial or prefilled syringe and a safety needle if possible. If the solution is drawn up from a vial then it should be injected within 5-10 minutes after filling the syringe to prevent any precipitation. **Shake the solution** well prior to drawing out of the vial and if a pre-filled syringe; shake just before injecting with a 21 to 23-gauge needle into the deltoid muscle or gluteus muscle. Both deltoid and gluteus sites are equally efficacious, but if any known failures, site or medication problems occur, please report to the FDA at 1-800-FDA-1088 or fill out the form online at <http://www.fda.gov/medwatch/report/hcp.htm>. For gluteal injection use a 1.5" needle. For deltoid injection use the non-dominant arm. If the client's weight is less than 60 Kg (142#), use a 5/8" or even 1/2" needle to achieve muscle penetration of 5mm. If weight is between 60 and 90 Kg (142# to 198#), a 1" needle should suffice, and if greater than 90 Kg (198#), a 1.5" needle may be required to ensure intramuscular administration. If patient is obese, greater than 70 kg and not tall, then they will need deltoid injections to maximize contact with muscle tissue rather than adipose tissue. **DO NOT MASSAGE THE INJECTION SITE.** There is no need to rotate

the site, as every-three-month injections will not scar. Document the dose, date, and lot number in chart by placing the medication sticker on the medication log sheet and document the site of injection on the exam form. Record the date of the next planned injection using the [DMPA Perpetual Calendar](#) and if possible, the whole year or four planned shots, on the reverse side of the [Menstrual Diary Card](#) for the client's use.

Follow-up Visits

Twelve weeks after the first injection (can be 2 weeks early or 1 week late), no sooner than 65 days for Medicaid payment, and no more than 91 days between injections, the client should return for another injection. A [DMPA Reminder Postcard](#) can be mailed or the [Menstrual Diary Card](#) used. Document and evaluate any side effects at revisits. Weight and BP should be done at the time of the second injection and yearly thereafter. Check the weight at subsequent visits on all women who complain of weight change or who had significant change at the prior visit. Do a pregnancy test before the second injection, if she was a same day start/restart or if she has not had any bleeding since the first injection. The client can use the [Menstrual Diary Card](#) to document abnormal bleeding pattern.

If a woman is over one week late, making it more than a 13 week interval, she may receive an injection that day only if the sensitive pregnancy test (25 mIU) is negative, and the same day start/restart guidelines are used meaning she agrees to back-up contraception for 7 days gets ECP if indicated, understands the small possibility of a false negative pregnancy test if unprotected intercourse in prior 2 weeks, and agrees to return in four weeks for a pregnancy test especially if no bleeding.

At the 8th consecutive injection, the client is to sign the [Birth Control Method Specific Informed Consent Form](#) documenting the counseling regarding prolonged DMPA use and hypoestrogenic effects and possible risks. The [Bone Health/Calcium/Osteoporosis Handout](#) could be given to the client as well. At annual revisits this consent form is to be resigned to document ongoing counseling was done regarding the hypoestrogenic effects of the method and she continues to choose DMPA over other contraceptive methods. The company making DMPA November 2004 added a black box labeling warning to the DMPA package insert instructing providers to not prescribe DMPA after 2 years unless no other contraceptive method is acceptable. While it is very unlikely that a woman in her mid-20's to her late 30's is at any more risk with DMPA use than from lactation (which is not a risk factor for later hip fracture). In women under age 18 or older than 45 who have been using DMPA without interruption over 2 years with risk factors for low bone density (see [Bone Health Guidelines](#)) encouragement to switch her method to one with estrogen should be done and if she does not, then advising her about the availability of bone density measurement may be appropriate to assist in the counseling and risk assessment for continuation of the method.

It is prudent to recommend smoking cessation, minimize alcohol, caffeine, and carbonated beverage intake, adequate calcium intake of 1000 to 1500 mg of elemental calcium (see [Bone Health/Calcium/Osteoporosis Handout](#)), and weight bearing exercise for all women, especially teens, including those using DMPA. Studies show that women with long term DMPA use have 6% less bone density than other women. After stopping DMPA, the bone density increases. DMPA produces a relative hypo-estrogen state and thin Caucasian smokers who are already at risk for osteoporosis may be counseled that DMPA may not be the best choice for them. However, in some populations, like New Zealand, some women have used DMPA for as long as 20 years and there is not an epidemic of bone fractures. Lactation is a hypo-estrogen state and

pregnancy is also a time of bone loss, yet women do not get irreversible osteoporosis from these events. Extended use, especially in adolescence, of DMPA may be different however and if peak bone density is not attained this could have serious consequences later in life. It is known that if a woman enters the menopausal years with osteopenia or low bone density then her risk later in life can be double that of a woman with normal bone density for hip fracture and hip fracture can be a major cause of death (see [Bone Health Guidelines](#)).

Possible Side-Effects

Heavy or Prolonged Bleeding: About 30% of women will have prolonged (more than 7 days/month) bleeding and 10% of women will have very prolonged (more than 15 days/month) bleeding after the first injection.

- Obtain a history of the amount (pads/day) and duration of bleeding.
- Encourage use of Menstrual Calendar Reminder Card to document bleeding pattern.
- Reassure client that irregular bleeding is expected with DMPA and only 50% of women have amenorrhea after 1 year (4 shots) and 80% by 2 years (8 shots).
- Measure hemoglobin and give iron as indicated.
- Do a pelvic examination and make sure normal cytology and no evidence of infection.
- Test for pregnancy as appropriate. Remember the method does fail sometimes.
- Assure women that bleeding decreases after repeated injections of DMPA and most women have amenorrhea with time.
- Verify the woman has no chlamydial or other genital infection because without treatment her bleeding will not stop.

Early Excessive Bleeding in first 6 months of use can be managed with:

- Consider giving the second DMPA injection early (no sooner than 65 days) to accelerate uterine endometrial lining atrophy. Although, this is unlikely to work if the woman has been using contraceptive hormones (progestin) for greater than 3 months prior to DMPA use because the endometrium is probably already atrophied from progestin use.
- Ibuprofen 400 to 800 mg three times daily or Naprosyn 500mg twice a day for 5 days can also decrease bleeding volume and recurrence.
- One or two cycles of oral contraceptive pills with more estrogen and a low dose of a weak progestin like norethindrone (a pill like modicon) may be prescribed to try to regulate bleeding. Although there can be spotting due to uterine lining atrophy, estrogen use in randomized trials did not decrease the bleeding more than placebo. NSAIDs did help the bleeding.
- If bleeding continues then refer for possible pelvic ultrasound and endometrial biopsy as fibroids, tumor, or endometritis are possible.

Amenorrhea: Amenorrhea is expected on DMPA. After twelve months 50% of women have amenorrhea and 80% by two years of use. Test for pregnancy if there is a question of pregnancy.

Inflammation of Injection Site: Examine the site for swelling, redness or infection. Advise warm compresses, elevation, and rest the area as appropriate. For significant cellulitis, antibiotics targeting strep or staph skin flora pathogens may be prescribed for 3 to 5 days but if no improvement in 48 hours she should be referred (consult the Family Planning Medical Director) as she may need additional antibiotics and/or surgical treatment.

Weight Gain: A small but steady weight gain of about 2 to 4 pounds a year is common on DMPA but not inevitable. The cause may be from an increased appetite and sedation from the use of this 21 carbon progestin, which is very similar to natural progesterone. Another progestin, megace, similar to provera is actually used to induce weight gain in AIDS and cancer patients. Many women can use DMPA without weight gain and in a trial comparing the IUD to DMPA in Thailand there was not difference. Share the [Getting Fit handout](#) with the client.

Headache: Evaluate stress and other factors, which may cause headaches. Advise ibuprofen, aspirin or acetaminophen, relaxation techniques, or other measures to control headaches. If headaches are severe or persistent, referral to primary care or to a neurologist is appropriate and consider discontinuation of DMPA.

Vaginal dryness or vulvar atrophy complaints: Topical estrogen cream can be used daily for 4 to 6 weeks (0.625mg conjugated estrogens/dose). If the client needs estrogen replacement for symptoms for more than six weeks, then it is too expensive to do both injections and daily estrogen and she should change to COC pills or Lunelle. Interestingly, one study has actually found a decrease in yeast infections in long time DMPA users due to loss of estrogen and glycogen.

Discontinuation of DMPA Injections

Fertility can resume promptly in some women 13 weeks from the last injection and if pregnancy prevention is desired clients should be advised they will need contraception immediately and if starting a different hormonal method at more than 12 weeks from the last injection then 7 days of backup is prudent since changing dose and formulation. Clients should understand that menses might be absent or irregular for over 9 to 18 months after the last injection but that ovulation could happen prior to menses. If pregnancy is not desired, alternate contraception should be started within 12 weeks of the last injection. Infertility evaluations are not usually indicated until 18 months from last DMPA injection. Amenorrhea evaluation should be begun if still no menses 12 months from last injection. At age 50 most women will not be using DMPA for contraceptive purposes and DMPA should be discontinued since the effect of DMPA on breast cancer in older women is unknown and bone density is a known concern.

Pregnancy with DMPA Injection

DMPA has never been shown to cause birth defects but the original androgenic, high dose OCPs did cause some genito-urinary anomalies hence the DMPA labeling. Many women have been pregnant at the time of injection or had the method fail and become pregnant while using DMPA and there have been no long term effects identified in these children, except one study where women using DMPA during the pregnancy had smaller infants, but this could be due to late diagnosis of pregnancy, unwanted pregnancy, or late prenatal care. Termination of pregnancy is not needed if DMPA exposure occurs. However, recommend her obstetrical provider be notified of her DMPA use in pregnancy and if problems develop, FDA reporting is advised.

D

iaphragm

History and Examination

Initial Clinic Visit

The standard medical history is reviewed and enlarged upon as clinically appropriate by the clinician. The minimum required physical examination is performed and recorded, and if needed, additional examination done as indicated by the history. Minimum laboratory tests are obtained and reviewed. Fit the diaphragm and have the client practice insertion with the provider rechecking placement prior to dispensing the method as there are a few clients that may not be able to place and remove the device. Inform the client about emergency postcoital contraception. For most clients it may be appropriate to give an EC prescription to take if a method failure occurs such as non-use or a hole found in the latex device.

Subsequent Clinic Visits

- Women newly fitted with a diaphragm should be scheduled for a return visit after several uses, about two to four weeks after the initial visit. Examine the client after she inserts the diaphragm to determine competency and to recheck for proper fitting. Some providers may choose to have the client return wearing the diaphragm for more than 6 hours to check for slippage and comfort;
- All women should receive an annual minimum required physical examination;
- Women should be refitted after every pregnancy, pelvic surgery, or weight change of over 10 to 15 pounds.

Contraindications and Precautions

- When fitting is prohibited by variations of anatomy such as pelvic relaxation (rectocele, cystocele) which would prevent pocketing the front rim of the diaphragm beneath the symphysis pubis, an anatomically short anterior wall, vaginal septum, or conditions which hamper self-reach into the vagina, notably thick abdominal fat, short fingers, or a deep vagina;
- Gynecological obstacles such as a client's reluctance in touching her own genitals, unless the partner wishes to insert the device. The partner must come in to the clinic to learn proper insertion;
- An inability to learn the proper method of insertion;
- Recurrent urinary tract infections. Advise ample fluids and voiding before and after intercourse. Also check the diaphragm, as it may be too tight and pressing too tight behind the urethra. Another option is to switch to a flat spring device as they are less rigid and cause less pressure, however they are more difficult to place correctly and should only be fitted in experienced diaphragm users;
- History of toxic shock or vaginal Staphylococcus;
- Allergy to rubber (latex);
- Allergy to spermicide;
- A study has shown a 22% failure if the diaphragm is used without spermicide and a 12% failure if spermicide is used. Therefore, efficacy depends on spermicide use;
- Intractable yeast infections or bacterial vaginosis.

Benefits

- Some protection from STD (especially bacterial);
- Holds blood during menses;
- Little interference with sex (may insert hours before);
- Some users report increased pleasure as there is more lubrication and even the diaphragm ridge may increase friction of the glans of the penis;
- Low incidence of side effects;
- Lower incidence of abnormal Pap smears.

Fitting of the Diaphragm

- The proper size is gauged from the pelvic examination and confirmed by insertion and inspection. The woman is asked to bear down (as though having a bowel movement) while the diaphragm is in place, to evaluate the fit. The largest size that fits properly should be used;
- The coil or flat spring is best for a normal vagina. The arcing spring is best for poor vaginal support, moderate prolapse, or marked anteversion or retroversion;
- Educate the woman, by means of a chart, instruction sheet, and self-examination, to recognize her cervix and pubic symphysis by palpation, both with and without the diaphragm in place;
- Check placement after insertion of the diaphragm. Have client remove the diaphragm. Review and educate until the clinician feels satisfied that the client has mastered the technique and is capable of determining that the cervix is covered by the diaphragm;
- The proper size diaphragm or a prescription is dispensed along with a supply of jelly or cream appropriate for the woman's sexual activity and she is told to return for more supplies as needed;
- Warn women using the diaphragm that oil-based lubricants and medications will damage the rubber and hasten deterioration of the diaphragm. Advise only contraceptive creams or gels or water-based lubricants with the diaphragm. See the condom section above for a more complete list of substances.
- Cleaning fitting rings. First, wash with mild soap and water to remove cellular debris then soak either in a 1:10 dilution of bleach for 30 minutes or 70% ethyl or isopropyl alcohol for 15 minutes. Rinse thoroughly with water and allow to air dry. Keep rings in a clean dry place between use.

Possible Side Effects

- **Allergy to latex or spermicide:** Most diaphragms are made from natural rubber latex and some individuals may have an immediate allergic reaction, including hives, swelling and even difficulty breathing. If a severe reaction then do not prescribe. It is possible to order a silicone diaphragm, in particular the Milex Wide-Seal (800-621-1278 or 773-736-5500; <http://www.milexproducts.com/products/other/diaphragms.htm>). Advise women to try a change of spermicide, use cortisone cream on vulva for a few days, and if the problems persist, change spermicide or contraceptive method. The client may try to use a different type of jelly, but since they are all detergent variants and most with N9, the woman may continue to experience what is usually not a true allergy but an inflammatory reaction to the detergent. Unfortunately the failure rate is increased without spermicide use. The client can also try removing device at 6 hours, the soonest possible, and rinsing well with water.

- **Increased vaginal infections:** Both yeast and bacterial vaginosis may be increased. Diagnose and manage infections as appropriate. If problems persist or recur frequently consider changing to a non-barrier method.
- **Increased urinary tract infection:** Advise women to drink fluids, before and after coitus voiding, and toilet paper wiping from front to back of perineum. If the client experiences frequent UTIs, consider changing to a non-barrier method.

Patient Method Education

The woman should be given written materials and counseled about correct use of the method to include:

- Diaphragm size and fit check with weight change or pregnancy and preferably with each annual exam unless long term user;
- Stretching and examining the device monthly and replacing if latex is cracked or brittle;
- Place a tablespoon of spermicidal jelly, NOT FOAM, into the center of the device so the jelly contacts the cervical os;
- Insert up to 6 hours prior to intercourse;
- Leave in place a minimum of 6 hours after intercourse and no more than 24 hours;
- Apply additional spermicidal jelly into the vagina in front of the device with repeated acts of intercourse;
- Rinse the device after use and store with no powders somewhere clean and dry.

Emergency Contraception

Overview

The original emergency contraceptive pills (ECP) consisted of high dose estrogen pills taken for five days, this was poorly tolerated and of unknown efficacy. Then a recipe of high-dose combination oral contraceptives ("Ovral") was promoted by Dr. Yutzpe. The only oral contraceptive pills proven to work for ECP are those containing norgestrel or levonorgestrel. All other oral contraceptives have not been well tested for efficacy as emergency contraceptives. Currently high dose levonorgestrel (LNG) only pills are the most effective ECP available in the United States. There is research to support the use of RU486 or mifepristone for EC but the dosage for EC is different than for abortion, the cost for mifepristone exorbitant and availability is tightly regulated in the United States.

ECP use can reduce the chance of pregnancy with unprotected midcycle sex from 15 to 30% to 2 to 5% with combination ECP. The high dose progestin only pills, "Plan B®", further reduces the risk of pregnancy to 1 to 2%, especially if given in the first 24 hours. Said another way, if 1000 women took 1.5 mg of levonorgestrel within 5 days for unprotected sex, only 12 would get pregnant compared to the expected 50 pregnancies and if the pills were taken within 24 hours then only 4 women would become pregnant.

An egg is only capable of being fertilized for 12-24 hours following ovulation yet viable sperm can persist in the reproductive tract for up to 3-5 days. ECP does not change sperm viability. High dose levonorgestrel ECP has been shown to block or delay ovulation and if it does not block ovulation then it probably does not work (Obstet Gynecol 2002; 100: 65-71). Failure could result from an already established implantation, an excessive lapse of time between unprotected intercourse and ECP ingestion, client failure to take the total dosage, or vomiting of the pills. It will take 3 hours to get therapeutic progestin serum levels to block ovulation but this level then persists for 24 hours (Contraception 2001; 64:327-351). It takes 7 days of daily progestin use to change cervical mucus or the endometrium hence this is not a likely mechanism for ECP.

There is now evidence to support dispensing two ECP packages, one for the emergent need and one for future need. Women getting the second package in a study (NEJM 1998; 339:1-4) were less likely to return to the clinic with an unwanted pregnancy and had used the ECP appropriately. Barrier users or new hormonal contraceptive users needing a backup method would also benefit from an advance ECP prescription in the event of an accident.

There is little reason for concern if the method fails because current low-dose oral contraceptives, or even high dose levonorgestrol, are not teratogenic. When the birth control pill first came on the market they contained 10 times the current progestin dose, and only if they were taken throughout the first four months of a pregnancy, they could cause virilization of a female fetus. ECP or birth control pills if taken when a woman is pregnant will not cause an abortion.

Indications

Ideally, ECP should be given as soon as possible, or less than 24 hours following unprotected sex. Unprotected sex implies the person is at risk of conception, a broken condom is a good

example but, a late or single missed birth control pill would not lead to an ovulation, so is not usually an indication for ECP. It is also unlikely 2 missed OCP's could result in ovulation although if the missed pills were at the start of the pill package following the end of the pill free week then ECP is a good idea. A recent study verified the use of ECP was effective up to 5 days after unprotected intercourse. It is not possible to predict when ovulation will occur, hence ECP should be given based on coital and not menstrual history. Remember, it is most effective in the first 24 hours, with almost three times more pregnancies prevented the sooner it is taken.

A single package of ECP can also be prescribed for future use should the need arise. For example, a woman choosing a barrier method could get a package of ECP to keep and to use in the event of a condom breaking. ECP could also be offered to women starting a new contraceptive method that requires a back-up method or if they are seeking an abortion but have not chosen an ongoing contraceptive method yet. Women should be counseled that ECP cannot and will not cause an abortion. If the ECP is given for future use, it is important to still provide teaching about the method and indications for use. Also caution women to make sure the ECP package expiration date has not passed or the ECP may be ineffective.

Physical Examination and Laboratory Testing

There is no required physical examination. Pregnancy testing may be appropriate if the last menstrual period was more than 28 days ago or if there was unprotected intercourse a week or more prior to the visit. For any client in whom the history may be unreliable, a pregnancy test is strongly recommended prior to emergent ECP because a pre-existing pregnancy needs diagnosis. Embryo implantation does not occur until 6 to 7 days following conception or fertilization and only after implantation is HCG made by the trophoblast. It may then take another day or two before there are detectable HCG levels. Therefore, the pregnancy test may not turn positive until 9 to 11 days after fertilization.

Visit Scheduling, Examination, and Documentation

Make every effort to facilitate a visit for the client but a phone prescription is acceptable after history and verbal consent. Use the [Family Planning / STD Visit Form](#) for clients seeing the provider, or [Emergency Contraception Verbal Order Chart Form](#) or [ECP Standing Order Chart Form](#) (if located outside of the clinic) for RN only visits to document the medical history, prescription, and follow-up plan.

Contraindications

The only contraindications are an established pregnancy or a desired conception from intercourse within five days prior to taking the ECP. ECP cannot selectively interrupt an unwanted conception. There are no medical contraindications to ECP even if estrogen containing pills are used because the half-life of the estrogen is only 8 hours and with consumption of only two doses of pills, the estrogen effects on clotting or cancer cells are negligible.

Precautions

- Theoretically, the use of any **medication changing liver metabolism**, like dilantin, could decrease the estrogen or progestin dose, making the ECP less effective. However, this risk is unproven and because it is the progestin that makes the ECP effective, and progestins are only slightly decreased by liver metabolism, it is reasonable to try the ECP.
- During **breast feeding**, long-term estrogen use may decrease milk supply especially if nursing is not well established, so the progestin only ECP is preferred. However, since ECP use is of short duration, estrogen-containing pills could be used. In unusual cases, Ovrette

or progestin only pills can be used to provide the adequate dose of progestin but it is really best to prescribe high dose LNG ECP or Plan B®.

Side-Effects

Nausea and vomiting occur in 15 to 30% of women taking combined ECP with estrogen. Use of the progestin only ECP still results in 5% of women reporting some vomiting. Taking the pills with food may help nausea. If prescribing the progestin only ECP, an antiemetic does not need to be prescribed. If antiemetic is still desired or if using estrogen containing ECP, then an over the counter Dramamine or Benadryl or prescription for phenergen tablets (25 mg) may be taken with the first dose and repeated one hour prior to the second dose. If the client vomits within one hour of taking either dose or visible pill fragments are seen with vomiting, the entire ECP, both doses, should be repeated. There is no evidence to support this practice but because ECP is safe and pregnancy undesired, repeating the vomited dose is prudent and in order to have the necessary sustained progestin levels, repeat the entire ECP prescription.

Treatment

Prescribe one 750 mcg levonorgestrel pill STAT orally and another one to be repeated in exactly 12 hours. There is now good evidence that taking both high dose levonorgestrel pills (1.5 mg levonorgestrel) at once rather than dividing the doses works just as well and this can be as an option for women who may not be able to remember the second dose on time (WHO Study. Lancet 2002; 360: 1803-10). If not using the 750 mcg levonorgestrel (Plan B®) pills, then use the ECP Equivalent Dose Table to select the pill number based on the pill type which will deliver the ECP Equivalent Dose of the standard “Yutzpe” or Ovral brand ECP prescription. The first dose should be taken while the woman is in the clinic and the second pills should be scheduled to be taken in exactly twelve hours. There is no evidence to support taking the entire combined OCP dose at one time, so this regimen needs to be divided dosing. There is a significant decrease in efficacy with ECP given later following unprotected intercourse, therefore it is important to begin ECP as soon as possible. It is good to also emphasize the importance of not delaying the twelve hour second dose to produce a true twelve hour interval and the sustained progestin effect.

“Yutzpe” ECP Equivalent Dose Table

Ovral	0.05 mg ethinyl estradiol 0.50 mg norgestrel	2 pills each dose
Lo-Ovral	0.03 mg ethinyl estradiol 0.30 mg norgestrel	4 pills each dose
Nordette	0.03 mg ethinyl estradiol 0.15 mg levonorgestrel	4 pills each dose
Levlen	0.03 mg ethinyl estradiol 0.15 mg levonorgestrel	4 pills each dose
Preven™	0.25 mg levonorgestrel 0.05 mg ethinyl estradiol	2 pills each dose. Also HCG test in kit.
Triphasil	0.03 mg ethinyl estradiol 0.125 mg levonorgestrel	Yellow pills only 4 pills each dose
Trilevlen	0.03 mg ethinyl estradiol 0.125 mg levonorgestrel	Yellow pills only 4 pills each dose
Ovrette	.075 mg norgestrel	14 or 20 pills each dose
Plan B	.075 mg levonorgestrel	1 pill each dose or 2 pills at one time

Follow-Up

Schedule a visit in 4 weeks for a repeat pregnancy test and contraception counseling. Pregnancy testing is especially important if there has been no menses. Spotting for a few days following ECP is common. The regular menstrual flow may occur early, later or at the expected time, and it can even be the same as a regular menses. However, 98% of women should menstruate by 3 weeks following ECP and if no menses has happened, then pregnancy is likely.

Supply condoms or other contraception if sexual activity will continue, because ECP will not protect against pregnancy from future coitus. Strongly consider a second ECP package because many women seeking ECP will later need another ECP prescription, especially if the woman has not chosen an effective ongoing contraceptive method.

The client may also receive that day a contraceptive injection or be given one package of pills to begin the day following ECP if the client does not want to wait for her menses to start the method. The same day start/restart guidelines must be consulted and used for the selected method. Since there are ECP failures and there could have been a pre-existing conception which cannot yet be detected at the time of the ECP, a pregnancy test at the time of ECP and again in 4 weeks is required in a woman beginning an on-going hormonal method started the next or same day. It is very important to emphasize the need for back-up contraception for 7 days when a same day start is done and a pregnancy test at 4 weeks after the ECP and same day start is required. The client also needs to know that beginning a hormonal contraception may cause irregular spotting although it might be slightly worse if very late in the cycle when the endometrium is already preparing for menses but by three months her bleeding pattern should normalize and in a study same day OCP start users had the same bleeding as menstrual week starts. If the woman reports multiple acts of unprotected intercourse, then it may be more prudent to wait until the menses to begin the hormonal method to decrease unnecessary hormone exposure if the pregnancy would be continued by the woman.

In the case of ECP failure or pregnancy detection at follow-up, the woman needs to be provided counseling about all pregnancy options. There have been a few cases of ectopic pregnancy following ECP and a report that the risk of an ectopic gestation increases from 1 in 50 to approximately 1 in 20 pregnancies following the use of ECP (*Contraception* 2003; 67: 267-69). However, according to the FDA labeling there was no increased ectopic risk following the LNG or Plan B ECP in the FDA application (*Journal of Reproductive Medicine* 2002; 47: 881-4). If the ECP fails it is important to advise early obstetric or abortion referral to make it is sure not an ectopic gestation. Women being given ECP for possible future use should be counseled to call the clinic and schedule a follow up appointment when they use the ECP so they can get a refill and/or an ongoing method.

IUD for EC

For the woman who wants an IUD for continuing contraception, a copper T380A IUD may be inserted within five to seven days after the sexual exposure. The LNG IUS, or Mirena[®] IUD, has not been tested for this indication. Always use the IUD guidelines and perform a pregnancy test before insertion of an IUD for emergency contraception. Additional use of Plan B ECP may be prudent to block ovulation and decrease pregnancy risk if recent unprotected intercourse. A two-week follow up visit is mandated to ensure no pregnancy especially since there may be an increased ectopic gestation risk. Remember about 2% of all pregnancies now in the US are ectopic and any contraception that reduces the chance of pregnancy also reduces the risk of ectopic gestation. Said another way, women using IUDs have fewer ectopic pregnancies than

women not using these methods because the IUD users have fewer pregnancies. However, any pregnancy that happens when an IUD fails is at greater risk of being an ectopic because the IUD is better at preventing intrauterine pregnancy than at preventing ectopic gestation.

Public Education

Currently there are efforts to increase public awareness and availability of ECP. 1-888-NOT-2-LATE is a phone resource to help women find clinics that provide ECP prescriptions or a local pharmacy that provides ECP.

Verbal Prescription and Standing Order Protocols

Purpose

To provide education, assessment and follow-up for emergency contraception when a provider is not physically present. If no onsite provider is available, Public Health Nurses or clinic nurses can consult with a provider, receive a verbal telephone order and provide pre-packaged ECP to individuals requesting ECP, using the [ECP Verbal Order Chart Form](#). Alternatively if the PHN has been trained and is located off site, then ECP can be dispensed using the below instructions under standing orders ([FP ECP Standing Order](#) and [PHSKC Standing Order Policy](#)).

Protocol

A client requesting emergency contraception will be assessed by the nurse for eligibility using these ECP guidelines. Those clients interested in ECP will become clients of PHSKC. The client will complete the PHSKC registration form. An [EC Verbal Order Chart Form](#) or if appropriate the [Client Consent for ECP by Standing Order](#) and [ECP Standing Order Chart Form](#) will be completed. A current blood pressure and a pregnancy test should be performed if indicated. It is extremely important to do pregnancy testing for all emergent ECP because failing to diagnose a pregnancy could result in inappropriate treatment. Precautions and contraindications should be noted on the chart form. The chart form may be faxed to the appropriate provider if requested for a verbal order however, many providers do not need it faxed for consultation, although this may be the route to obtain the prescription signature within 14 days of the dispensing. Please see [EC PHN Site Specific Instructions](#) for the contact numbers and exact consultation procedure for the specific site.

A telephone call is made if verbal order is needed to the designated provider for consultation and to request the verbal prescription. This verbal prescription can be relayed verbally by the clinic staff working with the provider if the provider can not come to the phone. Document on the form the provider's name, the time, the date, and the verbal prescription. The nurse can then dispense the pre-packaged ECP with standard education and counseling. The verbal order may be delayed at the time of service and obtained later, but the signature of the prescriber should be obtained by 14 days. This is to improve efficiency and allow the batching of prescriptions to prevent multiple clinic interruptions. The ECP standing order protocol which does not require a verbal prescription can only be used by off site trained PHN staff and this program is to be monitored annually using the [ECP Standing Order Program Chart Review Form](#).

Follow-up

If sexual activity will continue, ongoing contraception is imperative because ECP will not protect against pregnancy from future coitus. If a method is desired, refer to a PHSKC clinic in 1 to 4 days for an exam and a prescription. Referrals to other health and social services should be

made as needed. If emergent ECP is dispensed, a second ECP package for advance provision should be supplied as well. A follow-up phone call to the client within 24 hours is recommended if estrogen ECP was given to make sure no vomiting happened or need for repeat dosing. A clinic appointment at client's primary provider or at the local public health clinic should be scheduled within 4 weeks for a repeat pregnancy test and to obtain an ongoing birth control method.

PHN ECP Supplies

Emergency contraception pre-packs can be ordered through the pharmacy by using a pharmacy order form which can be obtained from the Downtown Pharmacy Site. A dispensing log is to be used including the lot number and product expiration by client in the event of a product recall.

Prescribing and Dispensing Laws

Prescription Medication can usually only be dispensed by pharmacies. Washington Pharmacy Code allows dispensing of contraceptives, and only contraceptives, by non-pharmacy persons at family planning clinics. However, ECP pills cannot be dispensed unless there is a valid and current prescription. A prescription can only be written or given orally by a provider with prescribing authority and this can include a written standing order if such a policy/protocol exists and is utilized. PHSKC has an approved policy for standing orders ([PHSKC Standing Order Policy](#)) and this is in place for ECP under the general direction of the Family Planning Medical Director ([PHSKC FP ECP Standing Order](#))

Fertility Awareness or Infertility Basal Body Temperature Charting

History and Examination

Initial Clinic Visit

The standard medical history is reviewed and enlarged upon as clinically appropriate by the clinician. Special attention should be paid to length and regularity of cycles. Signs or symptoms of vaginal infection should be evaluated and appropriately treated. Inform the client about emergency postcoital contraception if using FAM for contraception. It is appropriate to give an EC prescription prophylactically. Use [Fertility Awareness Chart](#) is available to teach charting and taking of the daily temperature, cervical mucous quality, menses, coitus, and even cervical position.

Subsequent Clinic Visits

Women newly instructed should be scheduled for a return visit three menstrual cycles after the initial visit. The record of menses, basal temperature, cervical mucus observation, coitus frequency, and symptoms should be evaluated and reviewed with the client.

Precautions/Contraindications

- Irregular menses;
- Inability to keep careful records;
- High failure rate, more appropriate for birth spacing;
- 85% of women under age 35 have regular cycles.
- Women with cycle lengths less than 26 days or more than 32 days are not good candidates for this method as their ovulation cannot be easily predicted.
- Couples must be able to abstain for 12 days if using the cycle beads.

Benefits

- Acceptable to many religious groups;
- Very helpful for timing planned pregnancy or for infertility evaluation;
- Teaches about normal menstrual cycle;
- No artificial substances involved;
- Low side effects.

Instructing the Client

- Offer referral to classes for fertility awareness birth control;
- During pelvic examination, have the client hold a mirror so she may inspect her cervix. Obtain cervical mucus. Show her how to test the mucus by stretching it between two pap sticks or two slides. Show her how to test stickiness by rubbing between fingers. Have

her insert and remove the speculum until she has mastered the technique of locating her cervix, if desired;

- Review the method of obtaining basal body temperature and show the client a sample temperature chart. Encourage use of a digital thermometer;
- Review calendar method and give the client a new calendar to record her cycle. It is generally felt that the calendar method is not reliable until there is documentation of at least three regular cycles and that by combining cervical mucous and temperature, the method's efficacy is greatly increased.
- Schedule a return appointment to review charts. Remind the client to return sooner if problems occur or she develops signs of a vaginal infection.
- If using the [Basal Body Temperature Chart](#) to plan a pregnancy, then ascertain the presence of a biphasic graph. Refer to a gynecology clinic if there is evidence of no ovulation. Emphasize with the client that the egg only survives 12 to 24 hours and sperm three to five days so coitus must be frequent and timed appropriately for pregnancy to occur (see Infertility section in Gynecology chapter).
- The Cycle Beads can be obtained and stocked in the clinic or the kit is available at www.cyclebeads.com. This kit with instructions and a necklace of colored plastic beads can make it easier for women to use natural family planning. A black ring which can only move in one direction is moved each day to a bead and the color of the bead determines the risk of pregnancy. The red bead marks the first day of menstruation, the 6 brown beads before the ovulatory window and the 13 brown beads following ovulation signify when the risk of pregnancy is low ("sex during brown beads"), and the 12 white beads are the time when pregnancy is most likely to happen. If a woman's menses begins before or on the dark brown bead this tells her that her menstrual cycle was less than 26 days and she may not be the best candidate to use natural family planning.

Implant Contraceptives

Overview

Implants are controlled release systems using a polymer to make a rod which is implanted into subcutaneous tissue to deliver synthetic progestin hormones directly to the circulation, bypassing the gastrointestinal and hepatic first pass effects. Because the implant use does not depend on the user, implant systems are highly effective, and have failure rates lower than sterilization.

Mechanism of action

Within 24 hours of insertion of any implant system, the circulating progestin levels are contraceptive but it takes 7 days before the cervical mucous becomes protective. Therefore, unless the system is placed within the first five days of the menstrual cycle, ovulation could still happen with the first cycle so a back-up method for the first 7 days at a minimum is needed. Following removal, levels quickly fall and in 48 hours the progestin is no longer detected in the serum.

Efficacy

These progestin only methods block ovulation when the progestin levels are high in the early years of use but even if there is ovulation the cervical mucus is thickened under the progestin effect and acts as a barrier to sperm (Fertil Steril 1998;69:714-21). There continues to be some ovarian follicular activity because without estrogen as with the combination OC there is incomplete ovarian suppression. This can be the reason bone density is preserved but irregular ongoing bleeding persists with the implant system unlike the complete amenorrhea seen with long-term DMPA use. Often the implant bleeding is cyclic, appears to be regular, and is typically not painful or heavy. The most common reason for a pregnancy is at the time of insertion if a pregnancy was not diagnosed or occurs directly following insertion. Late in the life of the implant system as the progestin levels fall ovulation may become more frequent and the rate of pregnancy was as high as 1 in 100 with Norplant in the 5th year of use. If a woman gets pregnant while using the implant, 30% of the pregnancies are ectopic gestations.

There are **3 implant systems** but only Implanon will be marketed spring of 2005:

The **Norplant System**[®] consists of 6 flexible silastic tubes with 216 mg of Levonorgestrel (LNG), and a typical daily release of 80mcg for the first 6 to 12 months, 50mcg by 9 months, and 30mcg for the remaining years of use. The Norplant system is approved for 5 years of use although there are therapeutic levels up to 7 years and in women over age 33 who weighed less than 70kg at the time of insertion, use to 7 years only had a cumulative failure of 1.9% hence extended use is possible (Contraception 2000;61:187-90). There was never a legitimate medical reason to halt the distribution and sale of Norplant but there were numerous law suits hence the company marketing Norplant is no longer selling the system because it was not profitable.

Jadelle[®] is a two implant version of Norplant[®], which was FDA approved but was never

marketed in the United States and it is not currently available. Jadelle® rods are 4.3 cm in length and 0.25 cm in diameter, each rod contains 75 mg of Levonorgestrel and the system releases 80 mcg daily initially, decreasing to 25-30 mcg daily by 9 months (Obstet Gynecol 2003; 102:24-6). The Pearl Index for Jadelle® is 0.24 over 5 years and the mean serum level of LNG was still 279 pg/ml at 5 years which is contraceptive so extended use may be possible with this system as well but has not been reported.

Implanon® is a single 4 cm length and 2 mm diameter implant system with the ethylene vinyl acetate (EVA) copolymer containing 68 mg of etonogestrel (ENG) with an initial release rate of 60 mcg ENG daily producing a serum level of ENG of 245 pg/ml by 3 days which declines slowly to a mean serum level of 176 pg/ml ENG by one year. A serum level of ENG greater than 90 pg/ml will block ovulation (Contraception 1993; 47: 251-261). This progestin does not block estrogen activity like LNG hence the overall effect of this system is slightly more estrogenic than the LNG systems. Hence the effect on the endometrium is different than the LNG systems with an increase in amenorrhea rates but conversely the irregular bleeding typical of implants can be heavier with the ENG system (Contraception 1998;58:99S-107S). There has not been a measured increase in prothrombotic effect or problem with this ENG system although use in women with estrogen contraindications has not been studied (Contraception 1998;58:93-8). Insertion of the single implant took a mean time of 1.1 minutes and removal took 2.6 minutes (Contraception 1998;58:79S-83S).

Benefits

- Three to five years duration of action depending on the implant system
- Easily reversible
- Decreased menstrual blood loss, cramps, ovulatory pain, and anemia
- Very high effectiveness
- Does not contain estrogen so can be used by many women
- High continuation rate especially in adolescent populations
- Not dependent on the user for efficacy
- Low dose of progestin exposure

Absolute Contraindications

For women with any of the following, the implant system should NOT be inserted:

- Suspected or diagnosed **pregnancy**, although unlikely the implant system would cause birth defects or abortion, it could delay diagnosis or care of the pregnancy.
- Known or suspected **breast cancer**.
- **Undiagnosed vaginal bleeding**. The implant system is associated with changes in menstrual bleeding and could make evaluation and management of abnormal bleeding difficult.

Precautions

Women with the following may be given an implant system if, in the judgment of the clinician, an alternative method of contraception would not be acceptable to the client or would increase the risk of an unwanted pregnancy. Documentation of the counseling needs to be made in the client's record and if appropriate the [Birth Control Method Specific Informed Consent Form](#) signed annually.

- Plans for **pregnancy** in the next year. The implant system should not be used in women who do not plan on long term contraception.
- Inability to tolerate irregular, frequent **bleeding**. The client must be aware that irregular bleeding is expected during implant usage. It is common to experience 15 to 20 bleeding or spotting days in the first 3 months of use although amenorrhea can occur in 20% of women. Up to 30% of women discontinuing use of an implant cite bleeding as the reason (Contraception 1998;58:99S-107S).
- History of **gall bladder disease, heart attack, angina pectoris, thrombosis, or cerebrovascular accident** are listed as contraindications by the company because the implant labeling is the same as that for estrogen containing pills. Research has documented that the progestin only systems do not change the coagulation factors, lipoproteins, cholesterol, or lipid profile hence it is unlikely to change the outcome of gall bladder or vascular disease. However, use the [Birth Control Method Specific Informed Consent Form](#) because of the package labeling and counsel that there could be a small unknown risk. If a thrombosis does occur with implant use notify the FDA MedWatch system using the pharmacy guidelines.
- **Cardiac anomalies**, which predispose to subacute bacterial endocarditis with a history of needing antibiotics prior to dental work, do not need prophylactic antibiotics for insertion and removal according to the 1997 American Heart Association Guidelines (JAMA 1997; 277: 1794-1801) because the procedure is an incision of scrubbed skin.
- **Chronic headaches, acne, or severe depression** which could be exacerbated by a progestin only method like the implant system. A trial with an oral progestin only pill (consider use of 2 tablets a day to more closely approximate the dose equivalent to the implant dose) for 2 to 3 months prior to insertion to make sure the implant will be tolerated. Approximately 10-15% of the implant system removals are for headaches.
- **Pseudotumor cerebri** was reported with Norplant use and it is likely to happen with other progestin only implants. Any woman with this history cannot use an implant.
- If **Allergy** is present to the implant, the EVA or vinyl of the implant, or to local anesthetics, betadine (iodine), or tape then these need to be avoided.
- Use of **anticonvulsant medication or other hepatic enzyme inducing medications**, like rifampin, phenobarbital, dilantin, and other chronic medications which can reduce the progestin serum levels and should not be used according to the package labeling. The provider should ascertain that any chronic medication would not cause rapid progestin metabolism and consequently subtherapeutic levels of drug leading to a loss of efficacy. There have not been pregnancies reported with concurrent implant and medication use so this is only a theoretical risk and it may be preferable to the long-term use of DMPA but documentation would be necessary regarding the need to monitor for method failure.
- Evidence of **liver tumor**, hepatic adenoma, or active hepatitis/jaundice is listed by the WHO as a contraindication to use although progestins are not toxic to hepatocytes and

have not been implicated in accelerating hepatic disease. Consult the patient's primary care provider and the Family planning medical director. It may be that the use of the implant is preferable to pregnancy or other methods.

History

The client should be given the PHSKC patient education handout titled [Implant Contraceptives](#) or brochure and the manufacturer package materials prior to an insertion visit so she may think about the method and formulate questions. The standard medical history should include menstrual history, depression, headaches, pregnancy plans, acne, and other questions relevant to possible implant use. The [Contraceptive Implant Procedure Form](#) must be completed. The client should be informed about the risks and benefits and of alternate contraceptive methods. The [Contraceptive Implant Insertion/Removal Procedure Consent Form](#) must be signed prior to the procedure.

Examination

Annual pelvic exam and breast examination are required for this method to confirm long-term hormonal contraceptive use is appropriate. The non-dominant upper inner arm between the biceps and the triceps is the site of the insertion and should be examined to insure absence of musculoskeletal or dermal defects like tattoos as these would mandate insertion in the opposite arm.

Laboratory Testing

Confirm by history and unless on menses, absence of pregnancy before implant insertion. A pregnancy test is required for all insertions. Hematocrit or hemoglobin testing to document baseline value may be indicated if the patient has an abnormal menstrual history or past history of anemia.

Who May Perform Norplant Insertions and Removals?

Insertion and removal must be done by a trained provider. Training may consist of attending a training class, reading training materials, watching training videos, and practice on a model. The [Contraceptive Implant Insertion or Removal Skills Documentation Form](#) must be used to document the training and approval for independent insertion or removal procedures. Each clinician should perform a supervised insertion or removal and then it is up to the discretion of the supervising physician to decide if the provider is then qualified to insert or remove implants without supervision. At least two removals for the Norplant system because of the increased risk of difficulties with this multiple implant system should be supervised and it is then up to the discretion of the supervising physician to decide if the provider is qualified to remove implants without supervision.

When to Schedule the Insertion and Back up Contraception

The implant is best inserted within five days of the onset of menses or of a terminated or delivered pregnancy. Insertions can be done at other times by ruling out pregnancy and documenting a plan to use a backup method for 7 days post insertion. If the client has had unprotected intercourse in the prior 2 weeks and has the possibility of an early pregnancy then she should return on her menses or after 2 weeks of abstinence or protected sex. In the unusual case of proceeding with an insertion in spite of the history of unprotected sex additional documentation of the counseling regarding the risk of pregnancy, the need for a

repeat pregnancy test in 2 to 4 weeks depending on sexual activity, and the caution regarding ectopic gestation risk if method failure is required. If the woman is subsequently found to be pregnant the implant system should be removed unless the pregnancy is terminated to avoid exposure to the fetus although it is unlikely it is a teratogen it is not reasonable to leave the system in place in the setting of a desired pregnancy. Women using oral contraceptives or an IUD may have an implant inserted at any time of the month, but should continue that method for one more week or until the onset of their next menses.

Insertion Visit

The insertion procedure is done in the clinic under local anesthesia and takes approximately 5 minutes if the consent and counseling have already been done. If there has been an interval of time since the counseling, confirm that there is no risk of pregnancy and repeat the pregnancy test on the day of the insertion. The insertion documentation should include the [Contraceptive Implant Insertion or Removal Procedure Chart Form](#), PHSKC implant procedure consent form, and the device consent form supplied by the company documenting the client read the company materials. The package and lot number for the implant system should be documented in the chart and a [Do Not Purge](#) sticker placed on the outside of the chart. Use the supplies and procedure set-up information list located at the end of this chapter when setting up for a procedure. Access to emergency supplies and treatment for allergic reaction or fainting should be available for these procedures. After insertion it is essential to palpate the implant system is in place with the client and if a removal all implants should be shown to the client. The client is given the [Post Implant Insertion or Removal Procedure Information Handout](#) and the warning signs of infection are reviewed with her. Women should be advised that the implant system does not provide protection against sexually transmitted diseases.

Follow-up Visits

Four to six weeks after insertion, the client should return to assess side effects, answer questions and evaluate any problems. The insertion site is inspected for infection, phlebitis, expulsion or other problems. The clinician should assure palpation of all implants and record this on the clinic record.

Possible Side Effects

- **Heavy or Prolonged Bleeding:** Obtain a history of the amount (pads/day) and duration of bleeding. Encourage the use of the [Menstrual Diary Card](#) to document the bleeding pattern. Reassure the client that irregular bleeding is expected with the implant system. Check a hematocrit or hemoglobin and give iron as indicated. Do a pelvic examination and test for pregnancy or infection as appropriate. Estrogen supplementation was not been proved to help with bleeding and theoretically it could change the cervical mucus and lessen efficacy so unless using a COC pill (which has contraceptive dose progestin) do not give estrogen alone. For heavy persistent bleeding in the first 6 months an OC taper and/or one or two cycles of a low dose COC pill might help but this has not been proven and likely is only providing temporary relief. In randomized studies, NSAIDs, similar to a dose like Naproxen 500mg bid for 5 days, significantly decreased the spotting episode and reoccurrence with Norplant use. As with all menstrual symptoms NSAIDS medications can decrease cramping, duration, and amount of flow.

- **Amenorrhea:** Test for pregnancy. If the pregnancy test is positive, there is a higher risk of ectopic pregnancy and consider early referral for ultrasound. If the client is pregnant and planning to continue the pregnancy, then plan for removal of the implant system. If the pregnancy test is negative, reassure the client that amenorrhea is common (20% of Implanon users for example).
- **Infection of Implant Site:** Examine the site for swelling, redness, inflammation or expulsion of implants. Advise the client to apply warm moist compresses for 10 to 15 minutes 3 times a day, elevate and rest the arm as appropriate, and to go emergently for possible incision and drainage if no response in 48 hours. For significant induration and erythema consider prescribing an antibiotic with staph and/or strep coverage. Re-evaluate the site in two to five days to assure infection has resolved and implant system has not been expelled. Significant infection may require removal of the implant. Make a note in the chart regarding the infection because at the time of removal one may expect more difficulty with scar tissue.
- **Implant site scarring or hyperpigmentation:** This can happen and even removal of the implant system is unlikely to reverse this change in the dermis. It is possible the EVA polymer with Implanon will have less inflammation because there is no barium was added.
- **Expulsion:** Use backup contraception. Replace the missing implant system if the patient chooses. Contact the company to see if a replacement kit can be provided at no cost.
- **Headache:** Evaluate stress and other factors, which may cause headaches. Reassure the client headaches often resolve in two to three months. Advise NSAIDS, relaxation techniques and have her keep a [Headache Diary](#) to find inciting events which could be reduced. If headaches are severe referral emergently to a hospital may be needed or if more chronic in nature refer to her primary care provider for management and evaluation. Removal of the implant system may be necessary if no other cause is identified. There is a rare condition, pseudotumor cerebri which has been reported to be increased in women with use of the Norplant system. The fluid in the brain increases and causes pressure and this can present with worsening and persistent headache for which hospitalization and treatment may be needed.
- **Progestin hormone side effects:** like mood changes, irritability, fatigue, acne, or hair loss can occur in the early months of implant system use. Often these can resolve but if not referral to a primary care provider to consider other etiologies like thyroid disease.
- **Weight Gain:** Long term studies have shown most women have no weight change with implant use. Use the [Getting Fit Handout](#) to discuss diet and exercise habits.
- **Ovarian Enlargement or Cysts:** Implants do not suppress ovarian function to the same degree as seen with combination oral contraceptive pills. Consequently there may be the development of functional ovarian cysts just as is found in normal cycling women. Most cysts will resolve in six weeks and only refer for ultrasound and possible surgery consultation if palpation of a pelvic mass persists.

Reporting Problems from the Implant Systems to the FDA

Any problems like allergic responses, site or product problems, or unusual reactions or problems like a thrombosis while using the implant system should be reported to the FDA at 1-800-FDA-1088 or fill out the form online at <http://www.fda.gov/medwatch/report/hcp.htm>.

Discontinuation of the Implant

The implant system should be removed at 3 or 5 years depending on the system in place. The implants should also be removed when the side effects cannot be managed to the client's satisfaction or if she is planning a pregnancy. The implant may be removed at any time of the menstrual cycle, and unless pregnancy is desired, **alternate contraception should be started immediately**. Hormonal contraception can be begun on the day of removal but because it is possible for ovulation to occur with implant systems, back up contraception should be provided or practiced for the 7 days to allow the new hormonal method time to equilibrate. If the woman is seeking pregnancy, consult the preconception guidelines and advise her to wait at least until after one normal menstrual cycle to allow the endometrial lining to recover from the atrophy present with implant use.

A **new implant system** may be inserted at the same visit if desired by the woman. Insert the new implant system into the prior site and use the same incision unless the client prefers an entirely new site for placement.

Removal Visit

The removal visit can take up to 30 minutes for a 6 implant system like Norplant®. Removal of the Jadelle® system took only 5 minutes on average (Obstet Gynecol 2003; 102: 24-26) and the Implanon system can be removed in 2-3 minutes. The implant system should be removed only by trained providers. Use the [Contraceptive Implant Insertion or Removal Procedure Chart Form](#) and [Implant System Insertion or Removal Procedure Consent Form](#) and provide the [Post Implant Insertion or Removal Information Handout](#). Use the list at the end of this chapter to set the supplies and equipment for the procedure. If an implant cannot be palpated imaging to localize the implant may be necessary before making an incision. The Implanon system is not radio opaque and cannot be seen on a x-ray and ultrasound would be have to be used for localization.

IMPLANT INSERTION OR REMOVAL SET-UP & PREPARATION

Supplies needed for implant removals:

Norplant system removal instruments, pre-packaged and sterilized to include:

- 2 curved hemostats
- 1 straight hemostat
- Norgrasper, modified vasectomy clamp
- #11 or #15 scalpel blade
- For Implanon removal fewer instruments may be needed but until there has been enough procedures it is prudent to be prepared.

All removal and insertion procedures need the following supplies:

Large gauze sponges 5 –10 #

2 sterile drapes

Blue pad (or some absorbent pad) for exam table

Set of sterile gloves

Betadine solution or other antiseptic if iodine allergy reported

1% lidocaine with epinephrine vial

An 18 G needle to draw up the lidocaine into the 5 to mL syringe

A 25G 1 ½ inch needle for infiltration into the dermis

Steri-strips and a pressure dressing (gauze wrap and tape) should be available if needed

Working gooseneck or standing lamp

Do Not Purge sticker

For insertions:

Implant system package obtained from the pharmacy, patient visit sticker applied to

[Pharmacy Implant and Intrauterine System Log](#) and record lot number, expiration, and insertion date on log and procedure form

When putting patient into the room, make sure:

1. Pregnancy test is performed and documented on FP Flow Chart **before** procedure.
2. Query about any UPIC in the past two weeks and document on form.
3. Weight, BP and LMP documented on procedure form and FP Flow Chart.
4. Document absence of allergy to latex, betadine, and lidocaine, or tape.
5. Lot number and expiration date of the implant kit written on the form prevents the insertion of implant kits that are expired.
6. All supplies laid out on the counter and Mayo stand covered with paper drape.
7. Implant consent form and procedure form labeled with visit stickers.
8. Verify patient has a copy of the manufacturer brochure in appropriate language and has read it, and if not, get a copy to her.
9. Do Not Purge sticker on counter ready to put on chart if insertion done.
10. Make sure emergency supplies are available if allergic reaction or the client faints.

Intrauterine Device (IUD)

Overview

Intrauterine placement of a foreign body has a long contraceptive history. The current devices consist of a plastic frame with either a copper (T380A) or progestin (LNG IUD/Mirena®) added to the design. Both copper and progestin change the endometrium and cervical mucous to interfere with sperm motility and prevent fertilization of the ovum. Only when the copper IUD is used as an EC (emergency contraceptive) and inserted after fertilization does it act to possibly interrupt implantation. Although there have been no recent studies and if there is a true concern, it would be prudent to prescribe ECP as a back up measure. The primary contraceptive effect is to prevent fertilization. The IUD efficacy is one of the best of all the reversible contraceptive methods (failure is 1/200 in the first year and 1/500 after that) and it does not depend on compliance. However, all IUDs have a risk of expulsion (T380A is 2.3% in the first year and LNG IUS is 4.9% over 5 years) and 10% to 20% of the time this can be without symptoms (bleeding, pain, and vaginal sensation of string or device). Overall, if the IUD is in place, it is reported to be as effective as female sterilization.

Who May Use an IUD?

The ideal IUD user has been described as age 25, multiparous, monogamous, and having no dysmenorrhea history. However, many women may not be “ideal” yet may still choose the IUD as their contraceptive method. Diabetic women may use the IUD, due to their increased risk of cardiovascular disease; the IUD is a better choice than estrogen containing contraceptives. The copper IUD may also be placed 5 days following unprotected intercourse to prevent implantation as an emergency contraceptive.

Benefits

- Reliable long term reversible contraception;
- No interference with sex;
- If copper IUD used then no hormonal effects and women would have the same menstrual cycles as if no contraception were used;
- Progestin LNG IUD releases a very low dose so few systemic side-effects. The Mirena®, the new levonorgestral IUD, contains 52 mg Levonorgestrel (LNG) and releases 20 mcg every 24 hours with only ½ of this absorbed into the serum, or about 10 mcg of LNG systemic exposure, which is 1/10 the progestin dose found in the current 20 mcg LNG birth control pill.
- Low cost. If the Copper IUD is used for 10 years it is the cheapest contraceptive method available.
- The T380A IUD is labeled for 10 years of use. But a large study suggests it could be used up to 12 years. (*Longterm Reversible Contraception*. 12 years experience with the T380A and Tcu220C. World Health organization. Contraception 1997;56:341-52). They studied 1396 women with the T380A for 7159 woman years with a failure rate of 1.9% and no pregnancy after 8 years of use up to 12 years of observation. However, clients choosing to use after 10 years need to understand the failure rate may increase to 1-2% depending on if the copper has dissolved, which can only be determined if the device is removed. It is best to individually counsel the patient. A woman over 35 has decreased fertility and use up to 12 years may be a choice if consented ([Birth Control Method Specific Informed Consent](#))

[Form](#)). The LNG IUD is effective for 5 years and in women older than 35 at insertion, it could work for 7 years.

- The LNG IUS, because of the progestin, will induce endometrial atrophy, prevent hyperplasia and endometrial cancer. It has been used in women on tamoxifen and even as a treatment for hyperplasia or menorrhagia.

Absolute Contraindications

- **Uterine anomaly** since the IUD relies on a normally sized uterus for contraceptive effectiveness. The uterine cavity must be able to accommodate the IUD so the uterus must sound to between 6 to 9 cm in depth. If a woman has a bicornuate or two uterine horns she would need a device in each cavity to ensure adequate exposure of the endometrium to copper or LNG (although this has not been studied) and likely there would be a higher rate of insertion difficulty and expulsion.
- Active **cervicitis or vaginitis** infections need to be treated prior to insertion.
- **Silicone, levonorgestrel, or polyethylene allergy** if LNG IUD to be used.
- **Wilson's Disease or Copper allergy** if an IUD containing copper is to be prescribed. These allergies are rare but have been reported with IUD use and resulted in systemic symptoms and rash. Copper allergy can be pre determined with appropriate skin testing. (Contact Dermatitis 1985; 13:343)(Ann Allergy 1978; 41:194)
- Undiagnosed vaginal bleeding with suspected **uterine or cervical malignancy** if treatment may be a hysterectomy, since contraception is then unnecessary.
- **Pregnancy and/or suspected fertilization.** The Copper IUD can be used as an EC if inserted within 5 days of the unprotected intercourse but ECP should be prescribed as well to maximize pregnancy protection. A negative HCG on the day of insertion must be documented, and the client must return in 2 weeks to repeat the pregnancy test as there is a risk of ectopic gestation with an IUD.
- **Anemia** with hematocrit less than 32% unless inserting the LNG IUD and in that case the LNG IUD can be a treatment for anemia. The copper IUD may increase the menstrual flow by 2 days and 1 pad or tampon in some women but others notice no difference.

Relative Contraindications

The following conditions need documentation prior to insertion. Counseling and documentation needs to be done regarding the risks or possible consequence of IUD insertion and usage. The [Birth Control Method Specific Informed Consent Form](#) should be completed when indicated.

- **History of ectopic gestation.** IUDs are better at preventing intrauterine pregnancies and a woman with a history of an ectopic already has a 1 in 12 chance that a pregnancy could be ectopic and women using the IUD, if a failure have a 30-50% risk of that failure or pregnancy being ectopic in location. However, the best prevention of an ectopic pregnancy is to use effective contraception and the IUD may be used in these women but the women needs to know if she thinks she is pregnant to see care immediately as her risk for an ectopic is quite high.
- If menorrhagia, metrorrhagia, or severe dysmenorrhea, consider LNG IUD.
- **Known abnormal pap** not yet treated or evaluated because if cancerous, than a hysterectomy would obviate the need for contraceptive. Consult with the Family Planning Medical Director prior to insertion if there are questions.
- **Immunodeficiency disease**, HIV, cancer chemotherapy, or chronic high dose steroids (oral cortisone 20 mg or more daily). These women should not have copper IUDs and only the LNG IUD if uterine bleeding treatment needed. There is no proof that the use of the IUD

leads to systemic infection or a worsening of an immune disease but these are labeled contraindications and documentation of the discussion of theoretical risk needs to be performed.

- **Anticoagulation** therapy, platelet disorders, or any condition reducing the client's ability to make clots if using the copper IUD. It has been reported that use of the LNG led to a worsening of menorrhagia with Von Willebrand's which is a disorder of platelet function found in 1% of the population, 75% of cases are mild and can be treated with OCP, avoidance of NSAIDS, and occasionally intranasal desmopressin. (Obstet Gynecol 2005; 105:1223-6)
- **Multiple sex partners**, or partner with multiple partners since the risk of acquiring PID is greater and may mean removal of the IUD to evaluate pain complaints or if no improvement with antibiotics after 2 to 3 days, may need device removal to treat PID. The IUD does not prevent sexually transmitted infections.
- **Nulligravidity** (no prior pregnancy). Intrauterine contraception is generally not the method of choice for the woman who has never been pregnant. Reasons include risk of infection, infertility, severe pain or syncope, and a higher risk of IUD expulsion.
- **Age greater than 50** because it is unlikely there will be more than a few years of fertility, it is not cost effective and the insertion may be more difficult. However, older women may not be good candidates for hormonal contraceptives and the IUD may be her only contraceptive choice. In addition, if a woman is choosing the LNG IUD and is planning to use HRT when she is menopausal, this IUD could be beneficial.
- Already **has an IUD** but it is either an **unknown type** or known to be un-medicated (i.e. Lippes loop). Clients need to know old un-medicated IUD's have higher failure rates although if only a few years of fertility left it may not be as beneficial to change. An x-ray can help determine the type of IUD and if unable to determine it may be prudent to switch (consult Family Planning Medical Director).

Types of IUDs:

- **TCu-380-A (ParaGard)** - Available 1988 to present, life span 10 years and could use up to 12 years if consents, contains copper, 2 thin, white strings.
- **Levonorgestrel IUD (Mirena®)** - owned by Berlex, FDA approved 12/2000 2 stiff dark brown strings, releases 20mcg of levonorgestrel every day, compared to Copper IUD in one study fewer PID infections, amenorrhea in 20% of users, 90% menstrual volume reduction for some women, is indicated for use in anemia and women with menorrhagia. Life span is labeled as 5 years but it has been shown to be active for 7 years in women older than 35 at insertion.
- **Progestasert** - Available 1976 to 2001, life span is 1 year, contains progesterone, 2 thin, blue-black strings. Failure rate was 3% to 5%.
- **Lippes Loop** - Available 1964 to 1985, life span indefinite, all plastic, 1 thick or 2 thin strings, A: blue, B: black, C: yellow, D: white.
- **Saf-T-Coil** - Available 1967 to 1983, life span indefinite, all plastic, 2 thin, green strings.
- **Copper-7 (Cu-7)** - Available 1973 to 1986, life span was 3 years, contains copper, 1 thin, black string.
- **Copper-T (TCu-200)** - Available 1976 to 1986, life span 4 years, contains copper, 2 thin, various (often light blue) color strings.
- **Dalkon Shield** - Available 1970 to 1975, life span was indefinite, all plastic, 1 thick, black string with knot. Remove due to risk of PID.

History

The standard medical history should include menstrual, STD, partner, pregnancy, mode of delivery, ectopic pregnancy, uterine anomaly or surgery, and allergy history. [The IUD Insertion Procedure Chart Form](#) is to be used for all PHSKC insertions to document appropriately.

Examination

Prior to IUD insertion the client needs to undergo a pelvic examination to confirm no cervicitis, vaginitis, or uterine anomaly detected. On the day of insertion, a baseline pulse and blood pressure should be recorded.

Lab Tests

A normal **Pap test** should be recorded on the chart within the past year. IUD use does not cause abnormal cervical cytology but treatment for abnormal cytology may be more difficult with an IUD string within the cervical os. If there is a possibility of exposure or risk, then a **gonorrhea** and **chlamydia** test should be done one to six weeks before insertion and results recorded on chart. A **wet mount and vaginal pH test** should be performed prior to insertion and if bacterial vaginosis is diagnosed, it should be treated before insertion, even if asymptomatic. If there are any concerns, pregnancy testing needs to be performed on the day of insertion to document a negative **HCG test** as well as a follow up test two weeks later if any instances of unprotected intercourse are reported. A recent **hematocrit or hemoglobin** result, within one to two years of insertion date, should be documented if a history of heavy menses.

IUD Consent Process

The screening history, examination, laboratory tests, and consent form are reviewed with the client prior to the insertion visit. The consent brochure from the manufacturer should be sent home with the client prior to insertion. To document counseling the [IUD Insertion procedure Consent Form](#) is signed for the procedure risks and the manufacturer or [IUD Device Consent Form](#) supplied with the IUD package is signed for the device risk. Key points should be emphasized and documented using the [IUD Insertion Procedure Chart Form](#). If necessary, the [Birth Control Method Specific Informed Consent Form](#) needs to be signed at insertion and at every annual visit. This allows documentation that the high-risk user was offered other contraceptive methods or removal every year.

Manufacturer's Brochures

The manufacturer's brochure must be read by all potential patients interested in either the T380A or LNG IUD. The ParaGard T380A Manufacturer's Brochure is available to print from the Family Planning website. The brochures can also be ordered from the Paragard website at <http://www.paragardiud.com/pi/index.htm>. Manufacturer's brochures for the Mirena LNG IUS can be obtained by calling 1-888-BERLEX4 and speaking to a representative or by talking to the sales associate assigned to the facility or email request with complete delivery address to mirenabooklets@aol.com. If specified Spanish versions of the materials can be obtained as well.

Time of Insertion

Insertion during the first seven days of the menstrual cycle is preferable because the cervix is more open and an early pregnancy is less likely. However, research has shown there can be fewer expulsions and insertion infections when the IUD is placed later in the cycle. So there is no requirement that the IUD be placed during the menses as long as absence of pregnancy can be documented or counseling provided about the IUD acting as an emergency contraceptive and

plans made for pregnancy testing in 2 weeks following insertion. If unprotected intercourse is reported within the previous five days consider prescribing ECP or even rescheduling if multiple episodes of unprotected intercourse have taken place and there is concern about the possibility of pregnancy. The LNG IUD has not been proven to work as an EC to prevent implantation and should only be used as such with careful informed consent and in combination with ECP. The LNG IUD takes up to seven days to change the cervical mucous and therefore if it is not inserted in the first seven days of cycle, then a back up method for one week is necessary (pelvic rest advised, so abstinence for 1 week should be enough). If the client has been using Mirena, low dose OCPs, DMPA, or cervical stenosis is suspected consider having the client use a COC with 30-35 mcg EE for 1-2 cycles and then plan the insertion during the withdrawal week which can be scheduled by asking the patient to stop the OC 2-3 days prior to the insertion.

Preparation for Insertion

Advise the client to take ibuprofen 600 mg or another NSAIDS medication 1 to 2 hours prior to the insertion. The client should eat within 4 hours of the procedure, as it will minimize their nausea if they have a vasovagal reaction and ibuprofen taken on an empty stomach will cause nausea. Doxycycline 200 mg or Azithromycin 1 gm one hour prior to insertion has been studied and it has not been shown to decrease IUD insertion infections however some providers may choose to use a single dose as antibiotic prophylaxis. If the client normally has antibiotic prophylaxis to prevent bacterial endocarditis, such as when she has dental work done, then she may want the same antibiotics prior to IUD insertion, usually amoxicillin 2 grams one hour prior to the insertion. The American Heart Association states that no antibiotics are necessary for IUD insertion (*JAMA* 1997; 227: 1794-1801), however, some patients and providers insist on using prophylactic antibiotics. If necessary, consult the list below.

1997 AHA Prophylactic Regimens

- Amoxicillin 2.0 gm PO 1 hour prior to procedure
- Ampicillin 2.0 gm IV or IM 30 minutes prior to procedure
- Clindamycin 600 mg PO 1 hour or 600 mg IV 30 minutes prior to procedure
- Cephalexin 2.0 gm PO 1 hour prior to procedure
- Azithromycin 500 mg PO 1 hour prior to procedure
- Cefazolin 1.0 gm IV 30 minutes prior to procedure

It is estimated that 5 to 15% of the USA population is allergic to penicillin and about 8 to 10% of those individuals are also allergic to cephalosporins. If respiratory problems or swelling/hives are reported with penicillin use, then use non-penicillin medication or no prophylactic.

IUD Insertion Procedure

Use the list at the back of this chapter for how to stock and set-up the equipment and supplies which will be needed. IUD insertion may be done by non-physician providers specifically approved by the Family Planning Medical Director using the [IUD Insertion Skills Documentation Form](#). The providers are trained to insert IUDs during supervised insertions with the Family Planning Medical Director who will then decide what further training is needed. The provider is responsible for completing the IUD Insertion Skills Documentation Form, which is then to be given to the site supervisor who will keep it as part of the employee's file. If any insertion procedure is felt to be too difficult then the provider is strongly encouraged to stop the procedure and allow the Family Planning Medical Director to reassess the patient and perform the insertion. All nulliparous clients are to be inserted only by a physician or the Family Planning Medical Director. Only prepackaged, sterile devices will be used and the lot number and expiration date recorded on the chart and the [Pharmacy Implant and Intrauterine System](#)

Log. A paracervical block could be provided to the patient for the insertion if the provider has been trained. If a paracervical block is to be done, document the patient has no lidocaine allergy, chart the procedure on the procedure form, use the IUD set-up instructions, and infiltrate no more than 20 ml of 1% lidocaine solution divided and injected at the cervical tenaculum site and at 4:00 and 8:00 of the paracervical vaginal reflection. For all IUD insertions, a support staff should attend the provider as an assistant and in case of an emergency. All sites providing IUD insertion procedures need to insure ammonia inhalant and emergency resuscitation supplies, including atropine is readily available and these emergency procedures are using the PHSKC emergency protocols in addition to these. Verify and document if any allergy to the antiseptic and if allergic to both betadine and hibiclens then use no antiseptic.

IUD Insertion Procedure Sequence

The typical sequence of events for the insertion procedure include the following:

- Bimanual exam to assess for nontender non enlarged uterus and position.
- Speculum to visualize cervix and antiseptic swabbing of ectocervix.
- Change gloves to sterile gloves, load IUD if easy insertion anticipated.
- If risk of intolerance to sounding or stenosis then wait to open IUD package.
- Tenaculum to cervix (anterior if anteflexed, posterior if retroflexed).
- Uterine sound passed, slow gentle pressure, depth measured.
- IUD package opened and loaded (if not already) and inserter guard depth set.
- Insert IUD.
- Cut strings.
- Remove speculum, observe for 5-10 minutes.
- If abnormal pain consider removal of the IUD as it may be malpositioned or has uterus intolerant to the device (still bill for procedure and device since these were performed).
- If perforation of the uterus occurs do not insert the device, monitor vital signs, hematocrit, and consider emergent referral to a hospital. Often midline uterine perforations do not require surgery, yet it is possible if there is bleeding or hemoperitoneum surgery may be needed. Do not insert the IUD device if perforation is suspected. If perforation is later diagnosed and the IUD is outside of the uterus, referral for surgical removal is needed because both the copper and the LNG IUS can increase inflammation, adhesions and possible bowel perforation. (Human Reproduction 2003; 18:990-3)

Insertion Documentation

The [IUD Insertion Procedure Form](#) is to be used. The outside of the chart is then labeled to denote that the client's chart needs to be kept for the life of the device or 15 years from the insertion date for medicolegal reasons (with the Unique Retention Stickers). The [Pharmacy Implant and Intrauterine System Log](#) should be kept on site to record the lot number and patient, should a recall occur.

Post-IUD Teaching and Instruction

- Instruct the woman in the importance of feeling for the IUD strings after each menses and teach the technique prior to leaving the clinic. Strings should be lightly touched and not pulled on. If the partner reports feeling strings then instruct to see the provider back. If cut too short it can be like a bristle but also if too long they can be more irritating. Rarely, it may be needed to cut the strings to just inside the external cervical os and this should be documented so later removal technique can accommodate this change.
- Tampon use will not remove the IUD.
- Pulling on the strings can remove the IUD or dislocate it from the fundus, and cause method

failure.

- Expulsion of the device occurs in 3 to 5 % of users, luckily many of these are symptomatic (pain, bleeding, frame felt with finger or sensation in the vagina of longer strings). More frequent string checking is indicated in the first few cycles and follow up visit should be scheduled for 6 weeks after insertion to perform an exam and assess for problems or expulsion.
- Remind women that irregular bleeding is common for first 3 months with LNG IUD use and amenorrhea can happen to 20% of women by one year of use and to up 60% of women after 12 years of continuous use of this method (new device at 7 years). The copper IUD may increase the menstrual period on average by 2 days and volume by 50% in some users.
- If cramping is bothersome, recommend an analgesic such as ibuprofen, aspirin, or acetaminophen;
- Suggest use of iron-rich diet and iron supplements as indicated for Copper IUD users. The [Iron in the Diet Patient Handout](#) is available if needed.
- Advise no vaginal penetration for 1 week post-insertion.
- Advise back-up contraceptive method if sex sooner than 7 days post insertion, especially if not inserted in first seven days of menstrual cycle.
- Remind users that if pregnancy happens, 1/3 to 1/2 can be ectopic, so early medical consultation is important.

Follow-Up Visits

Pelvic examination 6 weeks following insertion, preferably after the next menstrual period, offers the best chance of detecting an early expulsion. It is also important the client report back at the follow-up exam any detection of the IUD strings by her partner during coitus. The LNG IUD strings have been impregnated with iron for easy visibility but also may be a little stiffer and it is important at insertion that strings be left long enough to curl behind ectocervix to prevent pelvic discomfort.

Long Term Follow-Up

The Copper T380A device should be replaced every 10 years unless the woman consents to keep it for 12 years and signs the [Birth Control Method Specific Informed Consent Form](#). The Mirena[®]/LNG IUD device must be replaced every 5 years. A woman older than 35 at insertion may choose to keep the LNG IUS for 7 years if she signs the Birth Control Method Specific Informed Consent Form. If a woman with a T380A is in her 10th year of use and she is over age 45, it is probably better not to subject her to an IUD change (new device). Decreased fertility due to age as well as the continued effectiveness of the IUD will likely make a change unnecessary, however consultation with the Family Planning Medical Director may be appropriate. All women need their IUDs removed at menopause, except LNG IUD users who could choose to keep for endometrial cancer prevention if using ERT, but this is a decision she would make with her regular provider that will assume her health care at menopause. Although the LNG IUD/Mirena[®] was not labeled for HRT use, it has been used effectively for this purpose. Insertion or use of the LNG IUD for HRT is not to be done by the Family Planning program. Annual pap tests and pelvic exams are recommended for all IUD users.

Side-Effects and Complications

Adverse Reaction during Insertion: Consult the site PHSKC Administrative Guidelines in the Emergent Section. IUD insertion may produce enough pain and vasovagal stimulation to result in syncope, cardiac arrhythmias, seizures, or even cardiac arrest. These are rare events, but

the client should lie on the exam table until she feels capable of standing, and then be requested to wait in the clinic for at least 10 minutes post-insertion. If any dizziness is reported, the client's blood pressure should be checked, and if significantly lower than pre-insertion, she should rest in the clinic until it is back to normal. Sometimes ammonia inhalant can be used to help make the patient aroused while vital signs are taken and preparation for atropine is done.

If severe syncope occurs (BP under 70 systolic or pulse under 50):

- **Call for help.**
- Don't leave client unattended.
- Place client in shock position.
- If symptomatic bradycardia (pulse 40 or less), administer atropine 0.4-0.5 mg in a subcutaneous injection. Can repeat in 5 minutes if no response.
- Remove IUD if symptoms persist.
- If asystole, begin CPR, administer epinephrine SQ (0.5 ml of 1/1000), call 911.

Bleeding starting soon after insertion: Rule out anemia, infection or pregnancy. Consult anemia guidelines. Naprosyn 500 mg BID for 5 days or Ibuprofen 400 to 800 mg three times a day for five days may help diminish blood loss if begun before menstrual flow like on the first day of the menses. NSAIDS will decrease the release of prostaglandins and that will in turn decrease blood loss by 50% in some studies. Reassure the client that bleeding usually decreases after a few months. If the bleeding is between menses, check for infection and pregnancy. An empiric trial of metronidazole 500 mg BID for 14 days is reasonable to try because a subclinical endometritis can cause persistent spotting. However if the bleeding continues at 6 months post insertion, then referral to primary care or gynecology clinic is suggested for possible pelvic ultrasound and endometrial biopsy to see if hyperplasia, submucous uterine fibroids, or other etiology such as a platelet or coagulation factor disorder is present.

Cramping or pain: Pain associated with insertion or dysmenorrhea may be relieved by ibuprofen or other medication. Cramping during the first three months post insertion is common and is probably due to uterine muscle spasm. Check for possible perforation or partial expulsion by bimanual pelvic exam to assess for pain and looking at the string length. If the IUD is partially expelled remove the IUD and replace with a new IUD as appropriate. Rule out infection such as PID and perform a pregnancy test if any concern over irregular bleeding or missed menses. One-third to ½ of pregnancies in IUD users are ectopic.

Missing IUD Strings:

- May be due to expulsion, pregnancy, or perforation of the uterus or retraction into the nonpregnant uterus. Tell the woman to use an alternate method of contraception and come into clinic for an exam. If her period is late, she should come in emergently.
- When the client comes into clinic often the strings may be visible in the cervical os. If no strings are visible, insert the IUD string retriever or cytobrush gently into the cervical canal to feel for the IUD strings. Do not go into the uterine cavity unless the client wants the IUD removed because entering the uterine cavity may disrupt or cause an infection of the device.
- If the IUD strings are located, the strings may be fished through the os. If they cannot be found, the client should be referred for pelvic ultrasound to localize the IUD in the intrauterine cavity. The strings are not essential to contraception and many IUDs used in other parts of the world do not have strings. A client wanting ongoing contraception does not need to have strings to use the IUD and after confirmation by ultrasound or x-ray she should be advised additional imaging is not needed unless a change in menses or pain.

- To remove an IUD without strings use an IUD hook or alligator clamp or if the provider has not been trained to perform an intrauterine removal, then refer the client to the Family Planning Medical Director for removal.
- If the frame of the IUD is in the cervical canal, the IUD must be removed, as it will not provide contraception and is probably causing pain.

Expulsion occurs in about 3% to 5% of women over the lifetime of the device. If the IUD has been expelled a new IUD may be inserted if client desires, using the same guidelines as used for all insertions. Because there has been one expulsion, the risk of a second expulsion is slightly higher but often the reason for the expulsion was lack of fundal placement or uterine spasm. If this is a good method for the client, then it is worth a re-insertion. If it has been less than 90 days from insertion, then apply for a refund using the [IUD Refund Pharmacy Request Form](#) even if the device was lost, because the program can get either a refund or a replacement system.

Pregnancy with a device in situ: The possibility of ectopic pregnancy must be considered. In the event of an intrauterine pregnancy the IUD should be removed as early in pregnancy as possible if the strings are visible. This measure will decrease the risk of infected abortion. However, if the pregnancy is beyond ten weeks and the strings are still visible, refer for an emergent pelvic ultrasound to rule out a placenta previa or the possibility that the IUD is implanted in the placenta. If the IUD strings are not visible when pregnancy is detected, recommend referral for emergent ultrasound examination and gynecology consult, as the IUD removal will probably be complicated or not possible. The LNG IUD has not been associated with birth defects according to the package label but it does release hormone and best to not expose a pregnancy. IUD removal, if an abortion is planned, can be referred to the physician performing the procedure. If an ectopic pregnancy is diagnosed with an IUD in place, the IUD should also be removed as it is likely it is ineffective since pregnancy happened.

Uterine infection: A large study of IUD's and infection found 1 in 1000 women getting an IUD get PID in the first 20 days from the insertion. After that time, PID is not the result of the IUD but of being exposed to an infection. The IUD does not increase pelvic infections but the presence of a foreign body may complicate treatment and if the infection has not improved with antibiotics in 72 hours, the IUD should probably be removed after consultation with the Family Planning Medical Director.

Mucopurulence: It is common to see cellular debris, calcifications, and even purulence associated with the IUD string at the ecto cervix. The strings are a foreign body and stimulate a response. If the woman is asymptomatic there is no need to do anything unless chlamydial screening is indicated. If the woman is symptomatic cutting the string to inside the external cervical os may be needed as it is unlikely antibiotics can treat the string. Symptomatic (pain or bleeding) then consider frank cervicitis, PID, partial expulsion, or even pregnancy as an alternative diagnosis.

Actinomyces on Pap Test:

Actinomyces species are normal inhabitants of the human gastrointestinal tract, in both the oropharynx and the bowel. Under ordinary circumstances, *Actinomyces* species do not cross mucosal barriers. The asymptomatic patient may choose to keep the IUD if the *Actinomyces* is persistent (2 paps 12 months apart) and understands this could lead to a serious infection if not treated early so important to return if bleeding or pain. When removal of the IUD is done, no culture of the device is needed and re-insertion of a new device two to six weeks later without a

repeat Pap test is acceptable. *Actinomyces* is a rare problem. These bacteria can be found in many women not using the IUD, and changing the IUD is often more risky than following the asymptomatic woman. Consult the Family Planning Medical Director in these cases.

Condition	Action
Pap smear showing Actinomycosis-like organisms:	
a. No symptoms (no abnormal bleeding and no uterine pain on examination)	<ul style="list-style-type: none"> • Repeat the pap smear in 1 year • If <i>Actinomyces</i> are present on the repeat pap smear: <ul style="list-style-type: none"> a) Remove the IUD, wait one menstrual cycle and re-insert another IUD (give the patient alternative contraception during this time) b) Treat the patient with the IUD in place: give doxycycline 100mg bid for 14 days, then repeat the pap smear in 3 months c) Do nothing, and have the patient return if she develops symptoms of PID or bleeding between periods
b. Symptoms of PID present	<ul style="list-style-type: none"> • Remove the IUD after pre-loading the patient with an antibiotic (amoxicillin 500mg tid for 14 days) • Treat the PID • If the infection is severe, hospitalize the patient • Consider an ultrasound to rule out an abscess

Adapted from Contraceptive Technology, 17th edition, page 539.

Peipert JF. Actinomyces: normal flora or pathogen. Obstet Gynecol 2004;104:1132-3.

Removal of the IUD

- Removal is indicated if the IUD failed and pregnancy occurred. For example, an ectopic pregnancy with an IUD, even if treated medically, the IUD needs to be removed or at least replaced.
- This may be necessary because of severe cramping, bleeding, infection or simply on request.
- All women entering menopause after about six months of amenorrhea should have their copper IUDs removed, as it is easier to do before the loss of estrogen. The LNG IUD can be used in menopause so a woman could choose to keep it if it has been less than seven years of use. Any other postmenopausal woman seen with an IUD in place should have the IUD removed if it can be done in the clinic.
- It is safer and easier to remove the IUD during menses, but the device may be removed at other times in the cycle if indicated. Removal midcycle could permit implantation of a fertilized ovum that is in the fallopian tubes at the time of removal. If removed after day 7 of the cycle there is a very small risk (about 1% on day 14) of method failure from coitus within 72 hours prior to removal and ECP might be considered. For this reason, a woman could begin a hormonal contraceptive method one to two weeks prior to planned IUD removal.

- If a woman is planning to get pregnant it is prudent to advise her to wait till after one menstrual cycle to regenerate an endometrial lining without any copper or LNG exposure before conception is planned. Although there is no evidence this is necessary or evidence of increased rates of miscarriages. Evaluate the need for prenatal vitamins with the patient.
- Grasp the strings with a forceps and apply gentle steady traction. If removal is difficult, a sound may be placed in the endocervical canal for about 30 seconds to effect dilation. If removal is still difficult, the client should be referred to the clinic physician.
- Refer women with an IUD without a string to the Family Planning Medical Director for removal with an IUD hook or a long straight alligator forceps if the provider has not been trained to use the hook or forceps.
- If there is early removal or expulsion of the device before 90 days, the IUD Refund Pharmacy Request Form should be completed and the clean but used device should be returned to the vendor representative directly as soon as possible and within 3 months of the event so the clinic can get a replacement IUD kit. This possible replacement kit benefits the program but not the client as we have no guarantee of a replacement and charges cannot be refunded or reversed because an insertion procedure was still performed and product used.

The Berlex Company, makers of the Mirena® or LNG IUS provided a grant to the ARCH Foundation, Patient Assistance Program for Mirena, P.O. Box 220908, Charlotte, NC 28222-0908, phone 877-393-9071, and fax 704-357-0036, to provide free LNG IUS to women unable to pay for the device. The woman must complete the ARCH Mirena Form by printing this form from the ARCH Foundation website: <http://www.archfoundation.com/Application.htm> verifying she has no insurance coverage for the device and that she meets the financial eligibility criteria. The form is faxed to the ARCH Foundation and a device is mailed to the site usually within the week. The Paragard company (FEI Women's Health runs www.paragard.com) also has a patient assistance program (1-800-322-4966) and the form is posted on the PHSKC website Paragard Patient Assistance Program Form. If the patient is going to use a device supplied by the company through an assistance program then it is important that the encounter form note this by a specific billing code and keep the originals of the application form in the chart to document this was done.

IUD INSERTION SET-UP & PREPARATION

Supplies needed:

IUD insertion instruments, pre-packaged and sterilized to include:

- Single tooth tenaculum with 2x2 gauze clamped between the teeth
- Medium Graves metal speculum
- Uterine sound with gauze or material wrapped around the pointed end to prevent piercing of paper and kit contamination
- Ring forceps
- Scissors – preferably long handled and monitor sharpness
- 4 long cotton swabs and 2 small swabs for the endocervical canal, all with tape over the ends of shafts to keep from tangling (Antiseptic is poured over the swabs)

Blue pad (or some absorbent pad) for exam table end

Sterile gloves

Betadine solution

Exam lubricant to do bimanual exam

Working gooseneck or standing lamp

Sanitary pad for patient

Do Not Purge sticker

IUD package, patient sticker applied to Pharmacy Implant and Intrauterine System Log and record lot number, expiration, and insertion date. Record this information on procedure form as well.

Supplies if paracervical block

1. 1% lidocaine no more than 10 ml, use 18G needle to draw up into 10 ml syringe
2. Stainless steel 3 inch metal needle extender sterilized
3. 25G 1 ½ inch needle

Supplies for IUD removals or complicated insertions:

Ring forceps is the only instrument needed if a string is visible. For difficult removals, an IUD hook, string finder or cytobrush, alligator clamp, and tenaculum should be available. For cervical stenosis schedule during menses and if necessary use a method with estrogen to time the period. In rare cases it may require use a 4-5 / 5-6 metal Hegar dilator if trained for this.

When putting patient into the room, make sure:

1. Pregnancy test is negative and documented on FP Flow Chart.
2. Weight, BP, pulse, and LMP documented on procedure form and FP Flow Chart.
3. Query about any UPIC in the past two weeks.
4. Lot number and expiration date of the IUD kit written on the form prevents the insertion of IUD kits that are expired.
5. All supplies laid out on the counter and Mayo stand covered with paper drape.
6. IUD consent form and procedure form labeled and 2 holes punched at the top. Forms on top in chart. Verify patient has a copy of the manufacturer brochure in appropriate language and has read it, if not, get a copy to her.
7. "Unique Retention sticker" on counter ready to put on chart if insertion done.
8. Make sure crash cart on site, specifically ammonia inhalants and atropine if the patient faints and or experiences a vasovagal reaction.

Lactational Amenorrhea Method

Breastfeeding should be encouraged and supported by the family planning program. Many women can breastfeed and providers need to query regarding lactation in any woman with infants or small children. The American Academy of Pediatrics recommends babies be exclusively breastfed for the first six months of life. But the national average for mothers who meet this goal is very low at 14% according to a CDC report in 2004. Breastfeeding can prevent diarrhea, ear infections, and respiratory infections in the child. Breastfeeding can reduce a woman's relative lifetime risk for breast cancer (Lancet 2002; 360: 187-95). Lactation will burn calories and help the woman return to her pre-pregnancy weight. Consult the PHSKC obstetrical guidelines regarding specific lactation questions.

The Lactational Amenorrhea Method (LAM) is an effective contraceptive method. Lactational amenorrhea is by definition a woman who is breastfeeding her child and has amenorrhea. For up to the first 6 months post partum, this method can be 99% effective. To be considered 'fully breastfeeding,' a woman should breastfeed on demand with no nipple or nutritional supplementation to the child (no pacifier, bottles, or cereal). Usually the breastfeeding occurs at a minimum of every 6 hours. It is not known if pumping the breast manually provides the same degree of feedback and ovulation suppression.

Because ovulation can occur before the menses resumes, it is prudent to begin another contraceptive method at 6 months post partum or sooner if someone is not fully breastfeeding. It is also possible to have ovulation happen prior to menstruation and this is common in the setting of LAM and for this reason after 6 months additional contraception should be practiced.

Estrogen in the birth control pill can sometimes suppress milk production so progestin only or non-hormonal methods are best until milk production is well established but this can be as early as 6 weeks post partum. In fact a recent review (Contraception 2003; 68:233-238) found there was little evidence with current low estrogen dose combination OC's (COC), and if a woman had well established lactation she could try the COC and if milk production declined then return to the progestin only method. Effective contraception is important to space children 3 years apart and to allow time for lactation. Remember, any women with LAM, meaning fully lactating and with amenorrhea, likely does not need another contraceptive in the first 6 months.

LAM induces a hypoestrogenic state and it is common to have women complain of introital dyspareunia or genital irritation. Sometimes a water-soluble lubricant is helpful, or if condom use is not needed then a vegetable oil can be used. Rarely, topical estrogen could be used (conjugated estrogen cream, 0.625 mg/dose, apply topically at HS 3 to 7 times a week for 1 month, no refills).

Although it is true that most women can breastfeed, there are exceptions. Women who should not breastfeed are those who:

- Take street drugs or do not control alcohol use
- Have an infant with galactosemia
- Are infected with the human immunodeficiency virus (HIV) and live in the U.S. with access to adequate alternative nutrition for their child
- Have active, untreated tuberculosis
- Are undergoing treatment for breast cancer
- Take certain medications
- Women positive for Hepatitis B antigen can breast feed although the infant should be given prophylaxis and vaccination and many women with Hepatitis C infection can also breastfeed provided the viral titers are low. Specific risk assessments for individual patients should be done by the primary care or obstetrical and pediatric providers and not family planning.

Taking Medications While Breastfeeding

Approximately 10% of drugs are passed into breast milk. Advise clients to minimize drug exposure while lactating. Women can discard their milk, if necessary, as pumping will maintain lactation intervals, so they have more frequent feeds which will help prevent sequestration of the drug in the milk. Also, women can ingest the medication while breastfeeding, because milk is made constantly it may decrease infant exposure to peak drug levels.

Antibiotics to avoid:

- Ciprofloxacin
- Doxycycline
- Norfloxacin
- Ofloxacin
- Podophyllin
- Podophyllox
- Tetracycline
- Trimethoprim

Also avoid these antibiotics until infant hepatic maturation (6 weeks post partum) especially if the infant was preterm:

- Sulfamethoxazole
- Sulfisoxazole

Medications Absolutely Contraindicated During Breastfeeding

Medication	Reason
Bromocriptine	Suppresses lactation, may be hazardous to the mother
Cocaine	Cocaine intoxication
Cyclophosphamide	Possible immune suppression; unknown effect on growth or association with carcinogenesis; neutropenia
Cyclosporine	Possible immune suppression; unknown effect on growth or association with carcinogenesis
Doxorubicin	Possible immune suppression; unknown effect on growth or association with carcinogenesis
Ergotamine	Vomiting, diarrhea, convulsions (at doses used in migraine medication)
Lithium	One third to one half of therapeutic blood concentration in infants
Methotrexate	Possible immune suppression; unknown effect on growth or association with carcinogenesis; neutropenia
Phencyclidine	Potent hallucinogen
Phenindione	Anticoagulant; increased prothrombin and partial thromboplastin time in one infant; not used in the United States
Radioactive iodine and other radiolabeled elements	Contraindications to breastfeeding for various periods

(from American Academy of Pediatrics, American College of Obstetricians and Gynecologists for perinatal care, 4th edition. Elk Grove Village, Illinois: AAP; Washington, DC: ACOG, 1997)

Medication Exposures During Pregnancy and Lactation

Every woman in the general population has a 3 – 5% risk of having a child with a birth defect or mental retardation. Birth defects are the leading cause of infant mortality in the United States. Two important factors to consider when assessing the teratogenic potential of a medication are the stage of pregnancy at which the exposure occurred and the amount of medication taken. It is critical to evaluate each exposure on a case-by-case basis in order to give an accurate risk assessment.

If you have a pregnant or breast feeding patient who is currently taking, or considering taking, a medication, the patient needs to be counseled about potential adverse effects the medication could have on her fetus or infant. This counseling needs to be documented in the patient's chart. Providers and patients may contact CARE Northwest toll free at 1-888-616-8484 for consultation regarding possible teratogenics.

Some Human Teratogens: Proven, Possible, and Unlikely

February 2001

From: Shepard TH. Catalog of Teratogenic Agents, 10th ed. Baltimore: The Johns Hopkins University Press, 2001: xxv
Adapted from 10/03 Care Northwest Brochure

Some Known Teratogens

Radiation

Atomic Weapons
Radioiodine
Therapeutic radiation

Infections

Cytomegalovirus
Herpes simplex virus I / II
Parvovirus B-19
(Erythema infectiosum)
Rubella virus
Syphilis
Toxoplasmosis
Varicella virus
Venezuelan equine
encephalitis virus

Maternal & Metabolic Imbalance

Alcoholism
Amniocenteses
(before day 70 post-
contraception)
Chorionic villus
sampling (before day
60 post-contraception)
Cretinism, endemic
Diabetes
Folic acid deficiency
Hyperthermia
Myasthenia gravis
Phenylketonuria
Rheumatic disease
Sjogren's syndrome
Virilizing tumors

Drugs & Environmental Chemicals

ACE inhibitors (benazepril,
captopril, enalapril, fosinopril,
lisinopril, moexipril, quinapril,
ramipril, trandolapril)
Aminopterin
Androgenic hormones
Busulfan
Chlorobiphenyls
Cigarette smoking
Cocaine
Coumarin anticoagulants
Cyclophosphamide
Diethylstilbestrol
Etretnate
Fluconazole (high doses)
Iodides
Isotretinoin (Accutane)
Lithium
Mercury, organic
Methimazole
Methotrexate
(methylaminopterin)
Methylene blue
(via intra-amniotic injection)
Misoprostol
Penicillamine
Phenytoin
Tetracyclines
Thalidomide
Toluene (abuse)
Trimethadione
Valproic acid

Some Possible Teratogens

Binge drinking
Carbamazepine
Colchicine
Disulfiram

Ergotamine
Glucocorticoids
Lead

Primidone
Quinine (suicidal doses)
Streptomycin

Vitamin A
Zidovudine (AZT)
Zinc deficiency

Some Unlikely Teratogens

Agent Orange
Anesthetics
Aspartame
Aspirin (but aspirin in the 2nd
half of pregnancy may increase
cerebral hemorrhage during
delivery)

Bendectin (antinauseant)
Electromagnetic waves
Hydroxyprogesterone
LSD
Marijuana

Medroxyprogesterone
Metronidazole
Oral contraceptives
Progesterone
Lamivudine

Rubella vaccine
Spermicides
Video display terminals
Ultrasound



Overview

Lunelle is the brand name for a combination injection contraception that contains both a microcrystalline suspension of medroxyprogesterone acetate (MPA) (25 mg), a first generation 21 carbon progestin made for slow release, and estradiol cypionate (5 mg). The E₂C is metabolized quickly to 17-B-estradiol with a half life of 4 days so by five half lives or 20 days the E₂C is gone unlike MPA which has a half life of 14 days and is cleared much later. After injection as the estrogen levels fall the woman bleeds 2 weeks later and this becomes her period week, if she gets her shot every 28 ± 5 days then her period week is typically 2-3 weeks after each shot. It is very effective with a perfect user failure rate of 1 pregnancy per 200 women using Lunelle in the first year. The injection prevents ovulation and suppresses, but does not atrophy the endometrium and monthly bleeding happens in 96% of women, but amenorrhea does happen in up to 4% of cycles. MPA serum levels can persist up to 63 to 112 days, which means ovulation can be delayed after use up to 4 months.

Contraindications

For women with any of the following, Lunelle **should not** be injected:

- **Allergy** to Lunelle or Depoprovera in the past. There are chemicals in the injection preparation that can trigger rare allergic reactions.
- **Known pregnancy**, although there is no evidence of teratogenesis in women who inadvertently receive Lunelle early in pregnancy, they could delay entry into prenatal care because they do not recognize the pregnancy;
- Less than **6 weeks postpartum** from a term delivery;
- A **girl that has never had a menses** because estrogen will stop her bone growth. Once menarche is reached, even one menses, then endogenous estrogen levels have begun and exogenous estrogen is safe.
- Undiagnosed **abnormal vaginal bleeding**;
- Known or suspected **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of Lunelle could worsen their prognosis.
- Any condition that could worsen with **increased cerebral fluid** in the **brain** like a meningioma, brain tumor, or pseudotumor cerebri.
- **Use of aminoglutethimide (Cytadren)**: This drug used rarely to treat adrenal tumors or Cushing's disease interrupts the synthesis of cortisol, aldosterone, and estrogen by inhibiting cholesterol conversion. The drug induces metabolism of the DMPA, which may reduce the bioavailability of the DMPA, hence decrease effectiveness.

All known **estrogen contraindications** apply to this method because the injection causes serum estradiol levels to become quite high (200 to 400 mg) albeit for only 2 weeks. For women with any of the following, Lunelle, **should not** be injected:

- Women with a **personal history** of a blood clot or **thrombotic event**, deep vein thrombosis, pulmonary embolism, cerebrovascular accident, myocardial infarction, or coronary artery disease.

- Women with a **first degree relative with a history of thrombosis** that occurred spontaneously (no injury), during OCP use, or pregnancy may have inherited a thrombophilia. If they have **never taken estrogen or had a pregnancy** then Lunelle might trigger a thrombosis or blood clot.
- Women **35 or older who smoke** tobacco. Women smokers aged 35 to 44 may use 20 mcg OC pills only if they sign the **Birth Control Method Specific Informed Consent Form**. But, they cannot use Lunelle, because the high estrogen peak could be dangerous for these women.
- Women **older than 50**, because the risk for thrombosis or breast cancer may be greater than the risk of pregnancy.
- Women with **diabetes and microvascular disease** such as retinal or renal damage proven or suspected.
- Women with **hypertension**, even if treated, have an increased cardiovascular risk with the use of estrogen injection.
- **Active hepatitis with jaundice**, liver failure, and hepatic malignancy
- **Chronic active hepatitis** with abnormal liver enzyme levels. Often the result of a viral etiology like hepatitis B or C, but also a history of jaundice during pregnancy or chronic liver disease like Gilbert's disease. The high dose of estrogen might not be metabolized if the liver is not working.
- **Hepatic adenoma**. The old high dose pills used to be associated with benign hepatic adenomas, which could sometimes distend, enlarge the liver, and rupture causing bleeding. Recent literature states the low dose OC pills have not had this problem but Lunelle with the rapid high estrogen levels could do this.
- In women with **epilepsy**, Lunelle may be less effective due to **seizure medication** (except valproic acid) use. This includes carbamazepine, primidone, phenytoin (Dilantin), and phenobarbital. Estrogen lowers the seizure threshold in the brain and can increase the number of her seizures and the high estrogen levels could worsen her disease. The IUD or DMPA injections are the preferred hormonal contraceptive methods in women on antiepileptic medications.
- Use of **rifampin** for tuberculosis increases the metabolism of estrogen and could make Lunelle less effective.
- **Chronic medication use** that induces the **p450 hepatic** enzyme system may result in decreased Lunelle efficacy. Examples include some antiretroviral drugs used to treat HIV, troglitazone (Rezulin) an oral hypoglycemic medication, and cyclosporine, an anti-inflammatory drug used for transplant patients.
- Use of **oral antifungal** agents including griseofulvin, ketoconazole, fluconazole, and itraconazole may induce hepatic metabolism and may make Lunelle less effective.
- **Immobility** such as need for a wheelchair, non-weight-bearing long leg cast, major surgery defined as causing immobility for more than two days, or a long surgery for greater than two hours which will predispose to thrombosis. Need to discontinue Lunelle use 4 weeks prior.
- **Any patient with acute or recent serious illness or chronic serious cardiovascular, vascular, or renal disorders** which may be aggravated by thrombosis or fluid retention such as congestive heart failure, renal dialysis, artificial heart valve for which the client is on anticoagulants, Lupus, Kawasaki disease with prior CAD, and many more conditions. If a patient has a serious medical condition it is often prudent to consult the Family Planning Medical Director prior to prescribing an estrogen containing method because there may indeed be a risk not discussed in the guidelines.

- Known or suspected uncomplicated **migraine headaches**. Have the woman keep a diary of her headaches using the **Headache Diary** and if she notices the headaches are worse during Lunelle use, then discontinue the method. If frequent **vascular symptoms** like blindness or numbness, then refer to neurology if no prior evaluation and do not prescribe Lunelle as it could cause a stroke.
- **Active gall bladder disease**. Estrogen use can worsen stone formation and dilation of the bile ducts and Lunelle should not be used. If they have had their gallbladder removed then there is no risk with Lunelle use.

Precautions

Women with the following **may be given** Lunelle if an alternative method of contraception would not be acceptable to the client or would increase the risk of an unwanted pregnancy.

- **Plans for pregnancy within one year**: Client must understand that they may have amenorrhea, irregular menses, and may be unable to get pregnant for 6 to 9 months after the last shot was given.
- **Inability to tolerate irregular, frequent bleeding**: Client must be aware that irregular bleeding is common and expected during the first 3 to 6 months of Lunelle use. The average duration of menses with Lunelle is 6 days and the interval between periods averages 20 days.
- **Inability to make frequent clinic visits**, the injections must be given every 28 ± 5 days and can not exceed 33 days between shots.
- **Lactation**, although estrogen can decrease the quantity – quality of milk the Lunelle injection because of metabolism may result in less estrogen exposure than a 30 mg COC pill. If lactation is well established Lunelle could be tried after 4 weeks postpartum.

Benefits

- Highly effective
- Has estrogen which could preserve bone density for teenagers, in particular those who are in their peak years to attain bone density.

When to Administer

When beginning Lunelle, it is best to administer the first dose within five days of the onset of menses, so the woman will be fully protected from the time of the injection. If Lunelle is given more than 5 days from the start of the cycle, ovulation can occur. Lunelle will not act as an Emergency Contraception to prevent implantation because, with the slow release of progestin, there is no high progesterone dose effect. It takes one week for the progestin effects on the cervical mucous and endometrium to be established. Lunelle can be given at the time of abortion, both first and second trimester.

Women not sexually active, consistently using oral contraceptives, using an implant or an IUD may have an injection at any time in the month. For other women, the first injection can be that day only if a negative UCG test is documented and the **Contraceptive Revisit Form** is used documenting that the woman agreed to use a back-up method for two weeks, understands the possible risk of false negative HCG test if unprotected sex in last 11 days, and agrees to return for a four week follow-up pregnancy test.

Postpartum Lunelle should not be given until 6 weeks postpartum to avoid increased thrombosis. Lunelle will also suppress milk production and should be avoided with lactation.

History and Examination

The standard **Medical History Form** should be used and reviewed for risk factors. The physical examination is performed and recorded to include weight, blood pressure, cervical, breast, and pelvic examination. If delayed pelvic option is used, the pelvic must be done prior to the ninth injection or after 9 months of use or else they must sign the **Birth Control Method Specific Informed Consent Form**, using the Delayed Pelvic section of the guidelines. The client should be educated about the risks and benefits of Lunelle and alternate contraceptive methods. Complete the appropriate **Contraceptive Revisit Form** with each following visit.

Lab Tests

Pregnancy testing should be documented for most Lunelle starts or restarts and it is mandated prior to the second injection if there has been no vaginal bleeding since the initial shot. Because amenorrhea is rare with Lunelle, always consider a HCG test if there has been no bleeding. A hematocrit may also be indicated if the client has been experiencing heavy bleeding.

Injection Technique

The provider will write a drug order prescription for “Lunelle (DMPA 25 mg and Estradiol Cypionate 5 mg) injection monthly (28 days \pm 5 days not to exceed 33 days) for one year or until annual exam due.” A registered nurse can give the injections using a vial or prefilled syringe. The company will be selling it as a vial to start. **Shake the solution** well just before injecting with a 21 to 23-gauge needle into the deltoid muscle or gluteus muscle. Upjohn affirms both deltoid and gluteus sites are equally efficacious. For gluteal injection use a 1.5-inch needle. For deltoid injection use the non-dominant arm. If client’s weight is less than 60 Kg (142#), use a 5/8 inch or even 1/2 inch needle to achieve muscle penetration of 5mm. If weight is between 60 and 90 Kg (142# and 198#), a 1 inch needle should suffice, and if greater than 90 Kg (198#) a 1.5 inch needle is required to ensure intramuscular administration. If patient is obese, greater than 70 kg and not tall, then strongly recommend deltoid injections to maximize contact with muscle tissue rather than adipose tissue. **DON’T MASSAGE THE INJECTION SITE.** There is no need to rotate the site, as injections usually do not scar. Give the client a copy of patient product insert. Document the dose, date, site, lot number and expiration date in chart and record date of next planned on the **Menstrual Calendar Reminder Card** for the client’s use and in the chart.

Follow-up Visits

28 days \pm 5 days after the first injection and no more than 33 days between injections the client should return for another injection. The **Lunelle Perpetual Calendar** can be used. Clients can sign up for email reminders using the Lunelle website at <http://reminder.lunelle.com/>. Document and evaluate any side effects using the **Contraceptive Revisit Form**. Weight and BP should be done at the first 3 injections and yearly thereafter unless an abnormal trend is documented. Remember Lunelle contains estrogen and this can increase the blood pressure in some women. Check the weight at subsequent visits on all women who complain of weight change or who had significant change at the prior visit. Do a pregnancy test before the second injection, if she was a

same day start, has not had any bleeding since the first injection, or if she did not use a back up method for 2 weeks if needed. The client can use the **Menstrual Calendar Reminder Card** to document her bleeding patterns. Counsel woman to expect irregular bleeding the first few cycles but with time her period week will be regular. The bleeding will typically happen around 2-3 weeks after each injection when the estrogen levels fall. Using Lunelle for menstrual suppression has not been studied and should not be done.

If a woman is 5 days late, making it more than a 33-day interval, she may receive an injection that day only if the sensitive pregnancy test (25 mIU) is negative. The **Contraceptive Revisit Form** should be used documenting that she agreed to back-up contraception for two weeks, understood the small possibility of a false negative pregnancy test if unprotected intercourse in the prior 11 days, and agreed to return in four weeks for a repeat pregnancy test.

Possible Side-Effects

Heavy or Prolonged Bleeding: About 45% of women will have prolonged (more than 7 days/month) bleeding and 20% of women will have very prolonged (more than 15 days/month) bleeding after the first injection.

- Obtain a history of the amount (pads/day) and duration of bleeding.
- Encourage use of **Menstrual Calendar Reminder Card** to document bleeding pattern.
- Reassure client that irregular bleeding is expected with Lunelle.
- Do a hematocrit and give iron as indicated.
- Do a pelvic examination, do current normal cytology and infection tests if not current.
- Test for pregnancy as appropriate.
- Assure women that bleeding becomes more regular (around 6 days per month beginning 2 to 3 weeks following injection) after repeated injections of Lunelle.

Amenorrhea. Not bleeding on Lunelle happens for up to 4% of cycles and women should be reassured if pregnancy has been ruled out.

Excessive Bleeding with use can be managed with:

- Naproxen 500 mg 3 times daily for 5 days or Ibuprofen 400 to 800 mg three times daily for 5 to 10 days can decrease bleeding.
- Consider switching to DMPA injection to decrease estrogen to accelerate uterine endometrial lining atrophy.
- One or two cycles of oral contraceptive pills with weak progestin like norethindrone may be prescribed instead of a repeat Lunelle injection, to try and regulate bleeding although not proven to work.
- If bleeding continues, consider infection evaluation (gonorrhea and chlamydia tests) and referral for possible pelvic ultrasound and endometrial biopsy as submucosal uterine fibroids, tumor, or endometritis should be ruled out.

Inflammation of Injection Site: Examine the site for swelling, redness or infection. Advise warm compresses, elevation, and rest the area as appropriate. For significant cellulitis, antibiotics targeting strep or staph skin flora pathogens may be prescribed for 3 to 5 days but if no improvement in 48 hours she may need referral for additional antibiotics and/or surgical treatment.

Weight Gain: A steady weight gain of about 2 to 4 pounds a year is common on Lunelle. The cause is probably the increased appetite and sedation (lack of exercise) from progestin use.

Headache: Evaluate stress and other factors, which may cause headaches. Advise ibuprofen, aspirin or acetaminophen, relaxation techniques, or other measures to control headaches. If headaches are severe or with neurological symptoms, referral to neurologist is appropriate and discontinue Lunelle.

Allergic reaction: There are rare cases of hives or respiratory reactions following Lunelle or DMPA injections. Usually the allergy is to the vehicle and not the hormone but an allergic reaction can be life threatening. This would be a contraindication to Lunelle and DMPA and future injections should be avoided. Report these to Upjohn at 1-800-253-8600.

Discontinuation of Lunelle Injections

The client should understand that menses might be absent or irregular for over 6 to 9 months after the last injection. If pregnancy is not desired, alternate contraception should be started within 33 days of last injection. Infertility evaluations should not be begun until 9 months from last injection. Amenorrhea evaluation should be begun if still no menses 6 months from last injection. At age 50 women should not be using Lunelle for contraceptive purposes and Lunelle should be discontinued because the effect of Lunelle on breast cancer in older women is unknown and could be undesirable given the elevated hormonal peaks.

Reporting Problems from Lunelle Injection to Upjohn and the FDA

Since widespread Lunelle use is still relatively new, any problems like allergic responses, site, product, or unusual reactions or problems detected while using Lunelle should be reported to Upjohn at 1-800-253-8600. You should also call the FDA at 1-800-FDA-1088 or fill out the form online at <http://www.fda.gov/medwatch/report/hcp.htm>. DMPA has never been shown to cause birth defects but the original androgenic, high dose OCPs did cause some genito-urinary anomalies hence the DMPA and Lunelle labeling. There is also a single study of women with DMPA injection in pregnancy having smaller infants but this could have been due to late diagnosis of pregnancy and late prenatal care.



Overview

The **Oral Contraceptive Pill (OCP)** is used by millions of women. At any one time, 1 out of 4 women in America using birth control are “on the pill” and 85% of American women have used OCPs at some time. They were first available in 1960 and at that time the pill contained the equivalent of 120 mcg of Ethinyl Estradiol (EE) and 10,000 mcg of an estrane progestin. The current **Combination Oral Contraceptive (COC)** pills contain 20 to 35 mcg of EE and only 1000 mcg (some only 100 mcg) of progestin (see **Hormonal Products Comparison Chart** at the end of this chapter). **Progestin Only Pills (POPs)** contain less than half the progestin dose in a COC pill and no estrogen.

The progestin component is responsible for the contraceptive action of the COC. Progestin blocks ovulation, causes thickening of the cervical mucus, and atrophies the endometrium so sperm cannot survive or get to the fallopian tubes for fertilization. Ovulation is reduced by 75% with cyclic sub 50 mcg EE COC cyclic pill use. The estrogen component of the pill stabilizes the endometrium to minimize irregular bleeding, allows lower progestin dosing, and increases the serum hormone binding globulin (SHBG) levels to decrease free testosterone and circulating androgen levels.

If COC pills are taken every day within 4 hours of the scheduled time, with no missed pills, no vomiting or diarrhea, no antibiotic or other medication use which can change absorption or OCP metabolism, then the pregnancy rate is only 1 out 1000 women using the pill for the first year. However, users usually miss some pills or restart late after the pill-free interval making the actual failure rate 5% or 5 women out of 100 users get pregnant in the first year of use. Progestin only pills have a “perfect user” failure rate of 0.5% or 1 woman out of 500 users and the same “typical” failure rate of 5% in the first year. Progestin only pills contain only progestin at approximately 1/3 of the COC dose, so 50% of women ovulate while using the POP hence cervical mucus is the primary barrier to conception. POPs need to be taken every day within 3 hours of the same time with no pill-free interval or scheduled withdrawal bleeding days. The progestin dose is so low the cervical mucus could change to allow sperm penetration if the progestin levels fall with late POP pill use.

Benefits

- Decreased cancer - ovarian and endometrial cancer risk decreases by 40% after 1 year of total OCP pill use and 80% reduction after 10 years of use (*JAMA 1987; 257:796-800*). This protection lasts at least 15 years and most likely persists for a lifetime. Conversely, if a woman has been ovulating for 35 or more years then her risk of ovarian cancer increases by 300% (from 1% to 3%) lifetime risk. The protection against ovarian cancer is thought to be from the reduction in ovulation and the use of progestin induces apoptosis or cell death of abnormal ovarian epithelial cells.
- Decreased breast changes like cyclic and fibrocystic complaints, fibroadenoma
- Decreased benign ovarian tumors and cysts
- Decreased pelvic inflammatory disease
- Decreased rheumatoid arthritis
- Regulates and reduces menstrual bleeding
- Decreased endometriosis
- Decreased osteoporosis
- Decreased anemia
- Decreased menstrual cramps, ovulation pain & premenstrual tension
- Decreased acne and hirsutism
- Can adjust menses for vacations or if conditions require amenorrhea

- No interference with coitus

Pills are very safe and to put it into perspective, an interesting table was developed for risk comparison by Contraceptive Technology (17th edition, 2000), listed here below. Indeed, even things like using a ladder are far more dangerous than taking the modern low dose OCP; in the UK in 2002 approximately 35,000 people sought medical care for falling off a ladder and approximately 50 died. (Lancet 2004; 363: 1252).

Risk of death in a year for men and women who participate in...

Motorcycling	1 in 1,000
Automobile driving.....	1 in 5,900
Rock climbing	1 in 7,200
Playing football.....	1 in 25,000

Risk of death per year for women aged 15 to 44 from:

Using tampons	1 in 350,000
Having sexual intercourse (PID).....	1 in 50,000

Risk of death per year for women from:

Undergoing sterilization	1 in 38,500
Continuing a pregnancy	1 in 10,000

Legal abortion:

Before 9 weeks	1 in 262, 800
Between 9 and 12 weeks.....	1 in 100,100
Between 13 and 15 weeks.....	1 in 34, 400
After 15 weeks	1 in 10,200

Using oral contraceptives:

Nonsmoker	1 in 66,700
Age less than 35	1 in 200,000
Age 35-44	1 in 28,600
Heavy smoker (25 or more cigarettes per day)	1 in 1,700
Age less than 35	1 in 5,300
Age 35-44	1 in 700

COC Pill Absolute Contraindications

For women with any of the following, COC pills (OCPs with estrogen), should not be prescribed by the PHSKC Family Planning Program.

- Women with a **personal history** of a blood clot or **thrombotic event**, deep vein thrombosis, pulmonary embolism, cerebrovascular accident, myocardial infarction, or coronary artery disease.
- **Known pregnancy** or less than 3 weeks postpartum following a gestation of 24 weeks or greater.
- Known **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of COC pills could worsen their prognosis. A recent study of 4575 women with breast cancer and 4682 controls without breast cancer did not find any elevation of risk for being diagnosed with breast cancer from using the OCP (NEJM 2002; 346: 2025-32). This study provides reassurance that the use of the OCP will not increase a lifetime woman's risk of getting breast cancer.
- **Active hepatitis with jaundice**, liver failure, and hepatic malignancy because they cannot metabolize the OCP.
- Women **45 or older who smoke** tobacco. Women smokers aged 35 to 44 may only use 20 mcg pills if they sign the Birth Control Method Specific Informed Consent Form and are counseled to reduce to 15 or less cigarettes a day.
- A girl that has **never had a menses**, since estrogen will stop her bone growth. Once menarche is

reached, even one menses, then endogenous estrogen levels have begun.

- Known **migraine headaches with focal neurologic symptoms** like blindness, numbness, or vomiting, which make the risk of a stroke high, especially with estrogen use.
- Known carrier of a **hereditary thrombogenic mutation** like Factor V Leiden or Protein S or C deficiencies.

Progestin Only Pill Absolute Contraindications

For women with any of the following, progestin only pills should not be prescribed by the SKCDPH Family Planning Program.

- Known **malignancy of the breast or endometrium**.
- **Known pregnancy**
- Seizure medications, rifampin, and many chronic medications could accelerate the metabolism of the already low progestin dose rendering the pill ineffective.

COC Pill Relative Contraindications

For women with any of the following, oral contraceptives containing estrogen should not be prescribed unless the client insists COC pills are the only method she will use. She must then sign the [Birth Control Method Specific Informed Consent Form](#) and the provider must document the discussion about alternative methods offered and the client accepting the risk from estrogen containing pills. In addition, the 20 mcg EE pill dose should be prescribed unless documented intolerance and the patient understands her risk may be increased with increased estrogen.

- Women **under the age of 35 and heavy smokers** (more than 15 cigarettes a day) have an increase in cardiovascular events on estrogen and women could be asked to sign the [Birth Control Method Specific Informed Consent Form](#) particularly if there are other risk factors such as family history or obesity. At a minimum counseling regarding tobacco cessation should be documented.
- Women age **50 or older** need mammogram, lipid, menopause, and possibly bone density screening to adequately manage a hormonal prescription. For these reasons it is not a part of the routine family planning program services. We also recognize women over 50 can become pregnant but a non-hormonal method can be used or management with an outside provider.
- Women with a **first degree relative with a history of a thrombosis** that occurred spontaneously (no injury or pregnancy, and especially if clotting event when young) may have inherited a thrombophilia. If the woman wanting COC pills has **never taken estrogen or had a pregnancy** then a COC pill might be her first exposure to exogenous estrogen and it could trigger a clot. Remember many women could have an inherited decrease in the ability to stop a clot and yet they may never have a problem with a blood clot. One calculation published by an Italian research group stated that COC pills would have to be withheld from 90,000 women to prevent one DVT. Since only 1% of DVTs cause death, it makes no sense to withhold COC pills to women for just a family history. A study of women with blood clots found very few had a family history, which suggests family history will not predict many events. Even if these women with a family history had the \$300 worth of tests done to see if they inherited the gene, half the time the tests will be negative and she could still have a hereditary propensity to clot. Use the [Birth Control Method Specific Informed Consent Form](#) if a worrisome family history and no prior estrogen exposure to document she was told of the unknown and probably very small risk of blood clots when using estrogen. To put the risk of getting a blood clot in perspective, if one followed 100,000 women for one year, five of them would get a DVT (1% are fatal). If you then gave all these women COC pills, then 10 to 30 of them would get a DVT during the year, but if they were all pregnant, 60 to 100 of them would get blood clots. Increased venous thrombosis has been reported in OCP users of pills containing desogestrel. A recent study of clotting found a significant increase in clotting in women on desogestrel compared to other progestins. For this reason, avoid desogestrel in obese women, women who are relatively immobile, new pill users or women with no prior estrogen exposure, or women with other risk factors for clots. Desogestrel significantly increases SHBG over Levonorgestrel use and it is in the label that this progestin

increased DVT risk 1.7 over other progestins (Am J Obstet Gynecol 2004; 190: 332-7). A discussion paper on the cardiovascular risks also concluded that these “third generation” or low androgenicity progestins increased the inflammatory markers and the thrombotic risk over other progestins (Atherosclerosis 2004; 172: 281-6). You may refer for familial thrombophilia evaluation if client has first-degree relatives with a history of blood clots especially if an affected relative can also attend the visit, to the Hematology Clinic at Harborview Medical Center (see [Information About Referral to Harborview Medical Center Handout](#)).

- Known or suspected **migraine headaches**, which may be worsened on OCP use then estrogen is not advised. If frequent vascular symptoms like blindness or numbness then refer to neurology and do not prescribe COC pills. If migraines with vascular symptoms that are rare or in the distant past, give only 3 cycles and evaluate for exacerbation and consider using 20 mg EE2 products to lessen the estrogen withdrawal trigger for a headache. Have the woman keep a diary of her headaches using the [Headache Diary](#) and if she notices the headaches are worse during the pill free interval then consider estrogen withdrawal etiology and consider extended cycles or skipping the pill free intervals. Use of a 20 mcg ethinyl estradiol pill with continuous COC pill use can be considered using the [Menstrual Suppression Guidelines](#).
- **Chronic active hepatitis** usually from a viral etiology like hepatitis B or C or a history of jaundice during pregnancy or chronic liver disease. Question the client and if she reports jaundice or documented hepatitis with abnormal liver enzymes within past three years then send a liver panel. If she has had no jaundice or documentation of elevated liver enzymes in past three years, then the prescription can be begun on the same day as the baseline liver enzyme panel. If the liver enzymes on the baseline lab test are double the normal values then plan to repeat liver panel in 3 months and after one year of use. Refuse a COC pill refill if enzymes have worsened until consultation with Family Planning Medical Director. If the enzymes were more than double the normal value, a woman has impaired liver function and her liver cannot metabolize her COC pill. Estrogen is not toxic to the liver and it will not worsen liver function, but a low dose pill will become a high dose estrogen pill because metabolism is impaired and she is then exposed to the risks of thrombosis. The process of metabolizing the estrogen could possibly worsen her liver function.
- **Hepatic adenoma**. The old high dose pills used to be associated with benign hepatic adenomas because estrogen likely induced proliferation and these could sometimes distend, enlarge the liver, and rupture causing bleeding. Recent literature states the low dose pills have not had this problem but any estrogen containing prescription label will contain this warning. If someone has a known diagnosis of hepatic adenoma, estrogen is contraindicated.
- Suspected **pregnancy**, although there is no evidence of teratogenesis in women who inadvertently took low dose oral contraceptives during the first four months of pregnancy.
- Women with **diabetes and microvascular disease**, such as retinal or renal damage proven or suspected is an absolute contraindication to COC pill use. Retinal vessel damage is not usually seen till after 10 years of insulin use and is very rare in non-insulin users. Diabetic women on insulin are followed by primary care providers and should have regular eye, renal and lipid evaluations with these providers. Estrogen and progestin use may change slightly the insulin dose needed but COC pill use is safe, will not worsen their diabetes, and is preferable to pregnancy.
- Women with **hypertension**, even if treated, have an increased cardiovascular risk with the use of estrogen. Consider changing to a method with no estrogen, or if unacceptable, the 20 mcg estrogen pill with the [Birth Control Method Specific Informed Consent Form](#). If the blood pressure remains elevated or worsens after 3 months, then COC pill use should cease. Estrogen can increase blood pressure and fluid retention. This means COC pills can interfere with hypertension medications and treatment.
- In women with **epilepsy**, pills may be less effective due to **seizure medication** use. This includes carbamazepine, primidone, phenytoin (Dilantin), and phenobarbital (see later in chapter table on drug interactions). The Family Planning Program will not be prescribing 50 mcg estrogen dose pills because estrogen absorption and metabolism is very different in individual women. The woman on a high dose estrogen pill is exposed to potentially higher thrombotic risks. Estrogen also lowers the

seizure threshold in the brain and can increase the number of seizures. The IUD or DMPA injection are the preferred hormonal contraceptive in women on antiepileptic medications.

- Use of **rifampin** for tuberculosis increases the metabolism of estrogen and will make the pills less effective. During short-term therapy such as meningitis prophylaxis, continue the oral contraceptive but use a back-up method as rifampin use has been associated with many pill failures;
- **Immobility** such as need for a wheelchair, non-weight-bearing long leg cast, major surgery defined as causing immobility for more than two days or a long surgery (greater than two hours) will predispose to thrombosis and consider stopping the COC pills 4 weeks prior.
- **Airline travel**, especially if the flight is 8 hours or longer, has been found to increase the risk of blood clot in COC users 14x higher than non-users not traveling.
- **Any patient with acute or recent serious illness or chronic serious cardiovascular, vascular, or renal disorders** which may be aggravated by thrombosis or fluid retention such as congestive heart failure, renal dialysis, artificial heart valve for which the client is on anticoagulants, Lupus, Kawasaki disease with prior CAD, and many more conditions. If a patient has a serious medical condition it is often prudent to consult the Family Planning Medical Director prior to prescribing an estrogen containing OCP because there may indeed be a risk not discussed in the guidelines.
- **Metabolic diseases** like lactose intolerance or celiac sprue. If a woman has an inability to metabolize something the package labeling for the pills should be read carefully for any other ingredients contraindicated for that patient. For example, many tablets might use lactose, starch, or cellulose for binding the pill so it holds together. These ingredients are listed in the first section of the package insert where the pill is described. No OCP appears to have phenylalanine so women with PKU are safe in using OCPs however the package labeling should still be scanned for that particular tablet's ingredients including the spacer pills. The amount of lactose in the OCP tablets with lactose is quite small however if a woman developed a worsening of her diarrhea or lactose intolerance complaints, the provider could try and find an OCP with no lactose listed in the ingredients. It is important to remember each pill brand can be formulated differently and a generic version of the pill could still have different ingredients for formulation or holding the pill together.
- **Hydatidiform mole or choriocarcinoma** currently being treated, with elevated serum HCG levels, should not have COC pills until the HCG levels are normal. A large case study of women with choriocarcinoma found that women given COC pills while their HCG levels were elevated were significantly more likely to require chemotherapy than those that did not use exogenous hormones until the HCG level had returned to normal (which would be close to zero).
- **Obesity.** Women with a BMI of $\geq 30 \text{ kg/m}^2$ are at more risk for thrombosis and the use of estrogen can increase this risk. Women weighing more than 70 kg may also have higher OCP failure rates according to a study (*Obstet Gynecol* 2002; 99: 820-827). This has not been shown in other OCP studies but it is possible because obese women have a larger volume of distribution and a higher rate of medication metabolism and clearance. Norplant failures were 5x higher in obese women and the patch failed in 8% of obese women compared to only 1% of normal weight woman. Obesity is also linked to fertility and parity and perhaps these women have a higher threshold and need higher doses for ovarian suppression. It is possible phasic pills or even cyclic 20-25 mcg EE₂ OCP's should be avoided especially if prior OCP failure and instead prescribe 30 mcg EE₂ pills or consider continuous use of 20 mcg EE₂ pills using the menstrual suppression guidelines.
- **Allergy** to other pill components found in the pill tablet like lactose, iodine, or dye for example. Each pill brand, including generics can have very different ingredients use to hold the pill together. These ingredients can be found in the package insert labeling.

COC Pill Precautions

Women with the following may be given COC pills if, in the judgment of the clinician, an alternative method of contraception would not be acceptable to the client or would increase the risk of an unwanted pregnancy.

- **Undiagnosed vaginal bleeding** until diagnosis is established and managed. Although often COC

pills can be used to regulate irregular menses. If the COC pills regulate the menses there is usually no further need for diagnostic tests. A 3 to 6 month trial of COC pills can be a diagnostic maneuver, proving that the history of irregular menses was most likely caused by lack of regular ovulation.

- **Lactation:** The amount and possibly the quality of milk may be lessened with the use of estrogen in the first few months post partum, or before lactation and "let down" are well established. A recent review pointed out that the evidence for COC contraindications with lactation is scanty and recent studies with current 20-30 mg EE2 doses has not been performed. If weaning is desired, COC pills may be used to decrease the flow of milk. A progestin-only hormonal contraceptive is preferred, but if lactation is well established then a change to COC pills is possible and may be best to prevent pregnancy and if there are problems, change back to progestin only. In a women with lactational amenorrhea consult the [Lactation Guidelines](#) chapter as many of these women do not need another method especially in the first 6 months.
- **Active gall bladder disease.** Estrogen use can worsen stone formation and dilation of the bile ducts. If the gallbladder has been removed then there is no risk with COC pill use.
- **Chronic yeast vaginitis.** This may possibly be worsened by cyclic estrogen use. There is a study that found DMPA use, which reduces estrogen levels, decreased the number of yeast infections.
- Use of **oral antibiotics** in particular metronidazole, amoxicillin, ampicillin, and tetracycline, have been associated with case reports of COC pill failure while taking these and other antibiotics. The mechanism for the failure is probably a change in the gut flora so the enterohepatic absorption and circulation of the estrogen and progesterone change resulting in subtherapeutic levels. The most conservative advice is to use a back-up method for the duration of antibiotic use (see [OCPs and Antibiotic Use Handout](#)) although the current Contraceptive Technology edition does not think this is necessary with COC pill use, POP users should consider a back-up method. If the woman is on chronic, daily low dose antibiotics (like acne suppression with tetracycline or nightly Septra for pylonephritis prevention) use the [Birth Control Method Specific Informed Consent Form](#) advising the pill method may not be as effective as in a non-antibiotic user, but likely if no break through bleeding or diarrhea then most likely there are effective hormone levels. Do not begin these chronic antibiotic users on a 20 mcg COC pill since these are usually women being treated for acne and would benefit from 30 mcg of estrogen and potentially the daily antibiotic could make the estrogen level even lower.
- **Gilbert's Disease** (hyperbilirubinemia because of a reduced uptake of bilirubin). Gilbert's Syndrome is a common hereditary condition, which results in abnormal or delayed clearance of bilirubin by the liver so a mild unconjugated hyperbilirubinemia results, usually with normal liver enzyme function/levels and liver histology. Fatigue, stress, alcohol, starvation, and illness can trigger an increase in the bilirubin and mild jaundice but icterus is rare. Phenobarbital or other hepatic enzyme inducers can decrease these bilirubin levels. This condition is found in 8% of the US population with more men than women affected. It is prudent to avoid drugs cleared by glucouronidation, which would include hormonal contraceptives if the condition is severe such as current jaundice. However, hormonal contraceptives are not toxic to the liver and have been used by many women with only a mild impairment. It is reasonable to check the bilirubin at baseline and following a month or two of use to insure the level is stable.

How Some Drugs Reduce OCP Efficiency

There are several mechanisms by which therapeutic drugs can alter OCP effectiveness. The result of each of these mechanisms is reduced estrogen and progestin levels and, therefore, increased likelihood of ovulation and subsequent pregnancy. Five of the primary mechanisms are listed below.

- **Liver enzyme induction.** Some medications increase the activity of the liver enzymes that metabolize hormonal steroids. This enhanced metabolism reduces the level of steroids in the blood stream.
- **Elevated Albumin or protein** which bind the OC steroids. Some medications may enhance the production of these proteins which could bind with progestins in the blood, therefore a decrease in

the amount of free progestin available to suppress ovulation.

- **Vomiting or diarrhea or loss of small intestine surface area.** Medications that cause vomiting or diarrhea could decrease the absorption of oral contraceptive steroids. Surgical removal of bowel or diseases which change the intestines' ability to absorb steroids could reduce the serum drug levels.
- **Reduced levels of intestinal bacteria.** Medications that reduce the levels of intestinal bacteria may cause vomiting or diarrhea; this may decrease the amount of OC steroids absorbed through the intestine. Reduced levels of intestinal bacteria also can affect the body's ability to reabsorb estrogen. Estrogen passes through the liver into the bile and is then secreted into the intestines; there it is reabsorbed back into circulation. The re-circulation of estrogen is important to maintaining stable hormone levels.
- **User factors.** Side effects of some medications may cause a woman to decide not to take her OCPs. For example, side effects such as nausea may cause the client to miss taking her pill for one or more days, a particularly crucial event is she is using a lower dose OCP and if missing pills extends the pill-free week. Also, a user may become concerned about spotting or breakthrough bleeding due to a medication/OCP interaction and decide to discontinue the method.

***Oral Contraceptive Pill Use and Possible Drug Interactions**

Interacting Drug	Possible Effect	Recommendation
Rifampin	Demonstrated compromised OCP efficacy	Consensus that use of this potent hepatic enzyme inducer requires alternative contraception
Griseofulvin	Hepatic enzyme inducer	Demonstrated compromised OCP efficacy
Ketoconazole, itraconazole, fluconazole	Inhibitors of hepatic enzymes	Increased levels of EE, delayed withdrawal bleeding. Chronic use could decrease efficacy.
Phenobarbital, primidone, phenytoin, carbamazepine, felbamate, oxcarbazepine, topiramate, vigabatrin, primidone, ethosuximide, modafinil, lamotrigine	Reduced steroid levels. Hepatic mfo enzyme inducers.	No data have demonstrated reduced suppression of ovulation but caution still strongly advised
Troglitazone, cycloporine	Hepatic mfo inducers	Possibly reduce pill efficacy
Diazepam, chlorthalidone, tricyclic antidepressants, theophylline, buprenorphine	Prolonged elimination half-life and increased plasma levels of these agents	Suggest lower doses may achieve desired therapeutic effect in OCP users
Acetaminophen, aspirin	Increased clearance of NSAIDS	Some clinicians believe higher doses of NSAIDS may be required for adequate therapy
Some antiretroviral drugs: nelfinavir, ritonavir, amprenavir, and nevirapine	Hepatic mfo inducing so increased progestin metabolism	Could decrease COC efficacy
St. John's wort	Inhibitor of cytochrome P450 isoenzymes	Breakthrough bleeding
Valproic acid, gabapentin, tiagabine	No change	OCP efficacy unchanged, seizures could still change from EE use
Tetracycline, doxycycline, ampicillin, metronidazole, quinolone	Rare case report	Consensus that risk is not increased if only monotherapy and COC pill. POP risk much greater since lower progestin level
Acyclovir and AZT related drugs, Indinavir, Saquinavir	None documented	Can be used with OCPs

*The information on this table was obtained from the Micromedex.com site September 2004. It is possible this information can change, and it is the provider's responsibility to verify the information has not changed.

- **Use of higher dose estrogen pill**, more than 35 mcg of ethinyl estradiol, will not be prescribed unless the Family Planning Medical Director has been consulted and the client signs a [Birth Control Method Specific Informed Consent Form](#).
- Yasmin is different from other birth control pills because it contains the progestin drospirenone. This progestin is similar to natural progesterone and the drug spironolactone, which is listed as a

teratogen. In addition this newer progestin which has no androgen binding may have the same problems as seen with other newer progestins like desogestrel and gestodene in that the lack of androgen effect and increased estrogen effect (SHBG increase) could increase thrombotic risks and this has been reported (BMJ 2002; 324: 869). Drospirenone can also increase potassium levels. Women should not take Yasmin if they have kidney, liver or adrenal disease because this could cause serious heart and health problems. Other drugs may also increase potassium. After the first month of using Yasmin, a potassium level should be checked for women using Yasmin and the following medications:

- NSAIDs (ibuprofen {Motrin, Advil}, naproxen (Naprosyn, Aleve, and others) when taken long-term and daily for treatment of arthritis or other problems)
- Potassium-sparing diuretics (spironolactone and others)
- Potassium supplementation
- ACE inhibitors (Capoten, Vaotec, Zestril and others)
- Heparin

Progestin Only Pill Precautions

- Irregular bleeding
- Weight gain if appetite increases
- Increased acne possible since progestin only
- Inability to keep a regular schedule as these pills **must be taken within 3 hours** of the same time every day and if not then the woman needs a backup method for 2 days and if she misses 2 days of pills then backup for 7 days.

History and Consent

The standard medical history is reviewed by the clinician to confirm absence of absolute and relative contraindications. Counseling should be provided to ascertain ability to comply with daily pill taking. If contraindications do exist then document other methods discussed, patient's decision to not use other methods, and if appropriate sign the [Birth Control Method Specific Informed Consent Form](#). If the client has signed this consent form then she needs to sign it every year when she is given a prescription for the COC pills. Her risk profile may change and there needs to be documentation that she was offered other methods every year and continues to choose COC pills.

Examination

Baseline blood pressure, weight, and pregnancy testing (if needed) should be performed prior to OCP prescription. Although there is no increase in the risk of breast cancer with pill use **annual breast exam** should be performed to emphasize the importance of early detection and screening. There is a small possibility that cervical cancer, increased in long-term COC pill users due to the estrogen proliferative effect on HPV persistence cervical ectopy or glandular epithelium of the cervix, and for this reason **cervical cytology** should be considered for women at risk and the [Cervical Cancer Screening Guidelines](#) should be used. There is an option of delaying the pelvic exam and the [Delayed Pelvic Guidelines](#) should be consulted. Progestin thickens the cervical mucus and atrophies the endometrium and this can decrease the ascent of bacteria to the upper genital tract, thus one can find asymptomatic chlamydial infections in OCP users. All OCP users should be offered STD screening as per the PHSKC STD guidelines.

Prescribing Pills

Prescription medication can usually only be dispensed by pharmacies. Washington pharmacy code allows dispensing of contraceptives, and only contraceptives, by non-pharmacy persons at Family Planning Clinics. However OCPs cannot be dispensed unless there is a valid and current prescription. A prescription can only be written or given orally by a provider with prescribing authority.

- **First time COC pill users** can only get an initial supply of three cycles. This 3 month revisit is to ask

about complaints and to measure the weight and the blood pressure. These are to be recorded by a clinic nurse and any significant problems evaluated by the clinician. Make sure the client is taking pills correctly. Use the [Female Family Planning / STD Visit Form](#) or similar note at visit. She can then be given the rest of the year's supply, usually 10 (total of 13 cycles for a year's supply).

- **Ongoing OCP users or prior OCP users**, who have been on oral contraceptives for at least three months at the time of the initial or annual visit, are without problems, and have documentation of a normal blood pressure after 3 months of estrogen use in the past, may then be given a supply sufficient (13 months total prescription between annual exams) to last until her next annual exam.
- If **late for annual exam**, provision of additional pill cycles, two sets of 3 cycles or up to 6 cycles, can be given with provider discretion because the risk of pregnancy is greater than the risk of an abnormal exam. An emergency refill of pills (3 packages) may be given or phoned into a pharmacy for regular clients without problems. This must be recorded on client chart.
- If **outside records** are needed, OCPs can be prescribed after complete medical history, weight, blood pressure measurement, and if appropriate, pregnancy screening. Outside records should be reviewed and if the records document the client is current with her annual exam then she may be prescribed the year's supply of pills. She should not get a second year's supply without an annual exam with the Family Planning Program.

When to begin COC pills

- COC pills should ordinarily be **started on the first day of the next menses or the first Sunday closest** to the onset of menses. For Sunday start: if menses begins on a Monday the client should take 2 pills that day so it is a "Sunday" start rather than wait until Sunday at the end of the week; if the menses begins on or after a Wednesday then wait to begin on that Sunday. The Sunday start was designed to give women period bleeding during the week so by the weekend bleeding has stopped. However, Sunday start can be bad because women run out of pills on the weekend and may have a late restart on a Monday or later. A first menstrual day start may induce faster and more complete ovarian suppression and is recommended for more effective contraception but a day one start has been associated with more irregular bleeding when compared to a cycle day 5 start. Perhaps if the endometrium is built up and ready for menses it does need to shed to then be easily suppressed. If continuous OCP use for menstrual suppression is being prescribed shedding the endometrium first may help minimize irregular bleeding and a cycle day 5 start may be best.
- **Same Day Start/Restart** may be done if the patient understands and consents. This means the first pill is taken the day of the clinic visit and can even be done there in the clinic with teaching. This may be appropriate in women taking ECP, or who has recently been on pills and missed more than 3 days of pills, or who has had a history of irregular menses and waiting until menses will increase the risk of pregnancy. Documentation of a negative HCG test is required. Consider if the client also needs an EC prescription because regular dose OCPs will not act as an EC. The client must understand the need for a backup method for 7 days and that a pregnancy test should be done if indicated in 4 weeks, especially if no bleeding. Provide counseling to the client that when beginning OCPs it is very common to have irregular bleeding for 3 months and it has been shown to be no worse than when starting the OCP outside of the menstrual week. After 3 months of OCP use typically the cycles are regulated.
- **Rule of Seven's** is a simple way to teach patients regarding pill use. Basically, after 7 days of active pill or progestin use, cervical mucus is changed and ovulation blocked so after 7 days no back-up is needed. Conversely, a woman should never go more than 7 days without progestin use or she then needs back-up contraception.
- If **switching pill formulation or dose**, especially from a higher to a lower dose OCP it is prudent to recommend 7 days of back-up contraception in case the dose change results in hormone level change.
- Women starting COC pills **after the 1st day of menses** should use added protection for 7 days. If starting before or on the 1st day of menses then no additional protection is needed for that cycle.
- It is possible break through or irregular bleeding during the first cycle of the OCP may be reduced by

starting the OCP on day 5 rather than day one of the cycle. It is possible the menstrual bleeding is not completed as well with the day 1 start and results in later in the cycle bleeding (European J Contraception and Reproductive Healthcare 1998; 3:121-3).

- COC pills may be started **21 days post partum** in women choosing not to breast feed or on the **day of an abortion** for any pregnancy **less than the second trimester**. After 24 or more weeks gestation, do not start estrogen use until three weeks post-delivery or abortion to minimize the risk of increased thrombosis post delivery. By 2 to 3 weeks post partum, 30% of non-breast feeding women will ovulate and could potentially get pregnant.
- If using the **OCP for Withdrawal Bleeding Manipulation** then consult the Menstrual Suppression Clinical Guidelines.

When to Begin POPs

- Any time postpartum or post-abortion.
- The cervical mucus change takes 7 days, so backup contraception is needed for 7 days since ovulation is often not suppressed.
- It is very important that POPs be taken every day within three hours of the same time because 50% of POP users ovulate and the contraceptive protection is from cervical mucus changes. If not, the woman needs to use a back-up method for two days while she resumes regular pill taking.

Product Brochure

The manufacturer's patient product labeling is to be given to the client each time pills are dispensed. The PHSKC patient brochure on oral contraceptives ([Birth Control Pill Patient Handout](#)) is appropriate to give out to clients beginning OCP use.

Possible Side Effects

- **Nausea.** Taking the pill just prior to sleep, for example at the time of tooth brushing could help. The nausea is centrally mediated and is the result of the estrogen effect on the brain. The nausea is not the result of a local effect on the stomach but because the estrogen is working on the brain to cause nausea. Taking the pill in the morning may end up producing a "morning sickness" effect. Taking the pill at night makes the estrogen peak while one sleeps. Progestin methods usually do not cause nausea. If a pill change seems necessary, a 20 mcg estrogen pill could be selected. A progestin-only method of contraception may be needed if the estrogen is not tolerated.
- **Weight Gain.** In studies of large numbers of women OCPs did not significantly increase the weight of the population however individual women may respond differently to pill use. Weight gain is usually from increased food consumption and decreased activity. However estrogen use can cause some fluid retention in some women and then it is appropriate to try a 20 mcg estrogen pill and educate about exercise and a low-salt diet. Drospirenone is a new progestin derived from a spiro-lactone like molecule which is a diuretic, however, in studies there is no prolonged effect on weight and at one year a small increase in weight; perhaps because it is a progestin similar to natural progesterone and medroxy progesterone acetate, which can increase appetite and sedation (less activity). There is no proven OCP with a "better" weight profile than another OCP.
- **Breakthrough Bleeding (BTB) or Spotting.** BTB is when the woman reports having bleeding between the pill free days or scheduled withdrawal bleeding. BTB is defined as enough bleeding to need a hygiene product like pads or tampons and spotting is when no protection was needed. In the first 3 months of COC pill use and for the first year of POP use these events are very common and worse with missed or late pills. Continuation on the same pill for three cycles before switching brands should be encouraged.

BTB During First 3 months of pill use:

- **Reassure client** this is very common when first beginning OCPs and is often because the uterine lining is shrinking and shedding under hormonal influence.

- Be certain that the pill is being taken at the **same time or within 4 hours**, if COC pill, and 3 hours if POP, of a set time every day, and there have been no missed pills. Missed or late pills are the usual reasons for BTB or spotting.
- **Rule out other causes** of bleeding as appropriate by history and exam such as pregnancy, polyps, cervicitis, or other medication use.
- **Ibuprofen**, 400 to 800 mg three times daily or Naprosyn 500 mg twice a day beginning with menses, can reduce the amount of menstrual flow and the frequency of BTB or spotting. Menses or menstrual withdrawal bleeding is triggered by a drop in progesterone, which results in prostaglandin production. These chemicals then shed the endometrium by vessel spasm hence the pain and cramps.
- For early or midcycle spotting, a higher **estrogen** or phasic pill with increased estrogen midcycle could be tried after three cycles.
- For late-cycle bleeding consider a **progestin** with a longer half life pill such as one with levonorgestrel or norgestrel if already three months of OCP use.
- **Recent history of DMPA:** Injections could interfere with the OCP levels since DMPA is not completely cleared for 6 months after use. Because of DMPA's progestin effect on the endometrium to cause atrophy increasing estrogen may suppress BTB or spotting. An estrogenic pill like a 30 or 35 mcg pill or a weaker progestin pill may help. There are no published studies on the best formulation to transition women from DMPA to COC pills.
- **Vitamin C:** 1000 mg at the time of taking the COC pill for a week for some women may help if it increases the absorption of estrogen. Conversely if the woman is a regular Vitamin C user and then stops taking Vitamin C it may cause her endometrium to experience a drop in estrogen and this could trigger spotting.
- **Alcohol use** can also change the metabolism of estrogen so that the estrogen is metabolized slower giving higher estrogen levels. Using alcohol daily, binge drinking or stopping alcohol consumption could trigger some transitory BTB or spotting.
- **Tobacco use** induces metabolism of estrogen making some smokers more vulnerable to breakthrough bleeding and spotting.

After 3 months of OCP use:

- The endometrium has atrophied and the most likely etiology is missed or late pills, and irregular pill taking. For this reason **pregnancy testing** is advised if the woman presents with bleeding complaints.
- If unexplained breakthrough bleeding occurs in women established on the pill, do an **infection check** and evaluate for other sources of bleeding before pill change. If no etiology is found and the BTB or spotting persists after two cycles, referral is indicated to gynecology clinic to evaluate for uterine or ovarian pathology.
- In a randomized study of DMPA users, **supplemental estrogen did not help BTB**. This has not been studied in OCP users, but it is unlikely to help except acutely and since estrogen causes proliferation it could be counter productive with increased bleeding when the supplemental estrogen is stopped. Switching to a COC pill with a decreased EE2 dose for ongoing use might be considered since less estrogen means less blood lining to bleed from.
- **Breast Tenderness.** This will usually disappear within three cycles. If not, lower doses of estrogen may help. Instruct in obtaining and using proper bra. Discuss the possible role of caffeine. Some women may benefit from vitamin E 400 IU daily.
- **Headache.** Allow two to three cycles for adjustment and recommend aspirin, ibuprofen or acetaminophen. Use the [Headache Diary](#). Consider discontinuing oral contraceptives if headaches worsen with continued use. Milder headaches may improve with a change of pill formulation to one with less estrogen. If severe, persistent, or vascular symptoms like blindness or numbness develop, stop COC pill use and refer to primary care provider and possibly neurologist. Estrogen withdrawal headaches can decrease with cycle elimination and taking a 20 mcg OCP continuously without a

break for menses is an option using the menstrual suppression guidelines.

- **Watery vaginal discharge.** If excessive vaginal discharge is still present after two to three cycles, a lower estrogen pill may be tried. Rule out vaginitis or cervicitis.
- **Oligomenorrhea and Amenorrhea.** These are common with low-dose pills over time, due to lack of estrogen proliferation of endometrium. Menstrual changes are not harmful and the client needs only reassurance. If the woman strongly desires to have periods, a higher estrogen 35 mcg, dose pill may be tried. If there is any reason to suspect pregnancy (forgotten pills, symptoms, suspicious pelvic exam, etc.) or two missed menses successively, then a pregnancy test may be done as appropriate.
- **Depression and Irritability.** A low sodium diet may help if premenstrual mood changes. Hepatic metabolism of estrogen can deplete vitamin B6 (pyridoxine) so a 50 to 100 mg daily dose can be tried to see if mood improves. A lower estrogen and/or progestin dose pill may also help. If mood changes appear to be cyclic, then extended or continuous cycles could be tried.
- **Increased Blood Pressure.** Repeat measurement after a brief rest in the clinic. If the increase is sustained, consult and use the Family Planning Hypertension guidelines. If diastolic continues to be 85 mm or greater then the client can use COC pills only after signing the [Birth Control Method Specific Informed Consent Form](#), switch the client to a 20 mcg estrogen pill and repeat visit in 3 months with COC pill discontinuation if still hypertensive.
- **Acne and oily skin.** COC pills or estrogen cause an increase in hepatic production of Serum Hormone Binding Globulin (SHBG). SHBG then binds to free testosterone and androgens effectively reducing the free, which are the active, androgenic hormones. This is why all COC pills can reduce acne and hirsutism. Studies to get marketing labeling for acne reduction compare the OCP to placebo and not to another COC pill, so it is not a fair trial since other COC pills will also reduce acne. Probably the best pill to reduce acne would be a pill with 35 mcg of EE and low dose of a weak nonandrogen binding progestin like NET (Ovcon 35).
- **Decreased Libido.** This may be related to decreased circulating androgens or a decline in the natural estradiol surge mid-cycle (ovulation). There is one study that reported Triphasil improved libido and this may actually be related to the increased estrogen to progestin ratio during part of the cycle. Some women report more libido on higher dose estrogen OC's but this has not been well studied. Vaginal dryness may be managed with lubricants or increased estrogen dose. A review of sexual arousal and taking a sexual history is also important.
- **Chloasma (melasma).** Hyperpigmentation areas on the face are a great cosmetic concern. Occurrence is related to sun exposure, family history, and pregnancy, and can be due to estrogen levels especially pregnancy and COC pill use. Pigmentation can be reduced by avoiding all exposure to the sun. Use of a high potency sunscreen especially on the affected areas may benefit. Bleaching agents such as hydroquinone, or tretinoin in topical creams are frequently helpful. DO NOT prescribe these, only refer. If a woman develops chloasma during pregnancy or with COC pill use she is at risk to develop it with repeated COC pill use or pregnancy. Sometimes the skin changes are permanent even after pill discontinuation so women may choose to discontinue use of COC pills to prevent further discoloration.

Hormonal Product Comparison Table

The table at the end of the chapter compares the dose of estrogen and progestins of the different OCPs available. Consult the [Family Planning Program 28 Pharmacy Medication Order Form](#) for OCP brands currently on the PHSKC [Formulary List](#) and comparative price list. All the OCPs listed have similar efficacy in preventing pregnancy; however when switching formulations or doses it is prudent to advise backup contraception for 7 days. Use the **Hormonal Product Comparison Chart** at the end of this chapter to help make pill brand switches depending on the types of side effects. Generic OCPs are not on our formulary due to cost but OC generics are rated AB, meaning good therapeutic bioequivalence with serum levels of the drug that can vary 20% from name brand but this is still effective and most women do not notice any difference although the packaging and pill color can vary from brand product.

Choice of Oral Contraceptive Pill Type

- For **new starts** prescribe a pill on our PHSKC formulary pill which is low cost. The preferred starter pill for the program depends on the contract pricing and is typically the lowest estrogen dose pill at the cheapest price. There are very few studies comparing women on different pill brands but there are very few differences. If a woman is obese ($\text{BMI} \geq 30$) or weight > 70 kg, consider avoiding phasic or 20 mcg EE₂ products unless used daily as it is possible obese women need higher doses although if the patient has not had an OC failure and is stable on a certain brand then it can be her choice to stay on the very low dose product.
- Use the [Menstrual Calendar Reminder Card](#) to help patients track their bleeding and spotting.
- Because there is a significant increase in clotting in women on desogestrel compared to other progestins avoid desogestrel in obese women, women who are relatively immobile, new pill users or women with no prior estrogen exposure, or women with other risk factors for thrombosis.
- With **ongoing** pill users, if possible, refill with a pill prescription most like the one she “likes” or has been using.
- **Triphasic and Biphasic** preparations vary the doses of the two hormones in the pills depending on the time in the cycle. There is no medical reason to prefer phasic preparations and evidence suggests phasic OCPs have more BTB due to varying hormone levels. Phasic products are not recommended for extended or continuous use. In addition, phasic OCPs should not be used if a client is on a chronic medication that requires stable serum levels like a tricyclic antidepressant or an antibiotic.
- **No 50 mcg** estrogen containing pill should be prescribed without consulting the Family Planning Medical Director.
- If a pill **change** is made **for side effects** prescribe only 3 cycles of the new pill and having the client return to evaluate the effect of the change. Usually pill changes do not result in significant problems. For example, the PHSKC formulary changes frequently for cost reasons and almost all of the women changed do not return with problems. When making changes for side effects remember **estrogen** decreases spotting and acne but can worsen nausea, bloating, breast tenderness, and headaches while **progestins** decrease the amount of menses but can increase appetite, sedation, acne, and mood changes. Interestingly, in placebo versus OC studies the only side-effects reported to be different in OC users compared to placebo users were breast tenderness and nausea. So perhaps only estrogen dose is a measurable difference between pill brands. But women are individuals and many side-effects are subtle and difficult to measure.

Hormonal Product Comparison Table

*Brand Name	Estrogen				Progestin		
		Dose (µg)	Cycle Days	Type	Dose (µg)	Cycle Days	
MONOPHASICS							
FemHRT	PD	EE	5	1-28	NET	1000	1-21
Activella	PU	17B, E2	1000	1-28	NETA	500	1-28
PremPro	W	CE	625	1-28	MPA	2500	1-28
PremPro5	W	CE	625	1-28	MPA	5000	1-28
Alesse/Levlite/Aviane/Lessina	W/BE/DM/BA	EE	20	1-21	LNG	100	1-21
Loestrin 1/20 /Microgestin 1/20	PD/WAT	EE	20	1-21	NETA	1000	1-21
Mircette/Kariva/Mercilon	OR/BA	EE	20/10	1-21/24-28	DES	150	1-21
Minesse/Melodia		EE	15	1-21	GEST	60	1-21
Meliane/Harmonet		EE	20	1-21	GEST	75	1-21
Yasmin	BE	EE	30	1-21	DSP	3000	1-21
Desogen/OrthoCept/Apri/Varnoline	OR/O/WAT	EE	30	1-21	DES	150	1-21
Nordette/Levlen/Levora/Portia/Minidril	M/BE/WAT/BA	EE	30	1-21	LNG	150	1-21
Seasonale	BA	EE	30	1-84	LNG	150	1-84
Loestrin Fe 1.5/30 /Microgestin 1.5/30	PD/WAT	EE	30	1-21	NETA	1500	1-21
Lo/Ovral/Cryselle/Low-Ogestrel	W/BA/WAT	EE	30	1-21	NG	300	1-21
Minulet/Moneva		EE	30	1-21	GEST	75	1-21
Ovcon-35	BMS	EE	35	1-21	NET	400	1-21
Brevicon/Modicon/Necon/ Nelova/Nortrel/Genora	WAT/O/WAT/ WC/BA/RU	EE	35	1-21	NET	500	1-21
Ortho-Novum 1/35/Nelova 1/35E/Nortrel 1/35/Norethin 1/35/ Norinyl 1+35	O/P/WAT/WC/ BR/RO/SE	EE	35	1-21	NET	1000	1-21
Ortho-Cyclen/Sprintec/Cilest	O/BA	EE	35	1-21	NGM	250	1-21
Demulen 1/35/Zovia	SE/WAT	EE	35	1-21	EDDA	1000	1-21
Demulen 1/50 / Zovia 1/50	SE/WAT	EE	50	1-21	EDDA	1000	1-21
Ortho-Novum 1/50 /Genora 1/50 / Nelova 1/50M /Norinyl 1+50 /Ovcon 50	O/RU/WC/SE/ BMS	ME	50	1-21	NET	1000	1-21
Ovral	W	EE	50	1-21	NG	500	1-21
Evra® Patch	O	EE	20	1-21	D-Acyl NGM	150	1-21
NuvaRing®	OR	EE	15	1-21	ENG	120	1-21

*Generic formulations may produce serum levels within 20% of brand name formulations, are packaged differently, pills a different color even, but are as effective as brand product.
 Italics represents a brand available internationally outside of the US.

Manufacturer

BA = Barr

O = Ortho / Monarch = M

R = Roche

OR = Organon

DM = Duramed

WC = Warner Chilcott

RU = Rugby

PD = Parke Davis/Pfizer

WAT = Watson

BE = Berlex

W = Wyeth

P = Pharmacia

BMS = Bristol Myers Squibb

PHASICS	Estrogen				Progestin		
			Dose (µg)	Cycle Days	Type	Dose (µg)	Cycle Days
OrthoPrefest	O	17B/E2	1000	1-28	NGM	90	3 days/on 3 days/off
Ortho-Novum 10/11 Necon 10/11/Jenest-28	O/WAT/OR	EE	35	1-21	NET	500 1000	1-10 11-21
Estrostep 21	PD	EE	20/30/35	1-5/6-12 /13-21	NET	1000	1-21
Cyclessa	OR	EE	25	1-21	DSG	100/125/250	1-7/8-15/416-21
Ortho Tri-Cyclen/ Trinessa/Trisprintec	O/ W/B	EE	35	1-21	NGM	180/215/250	1-7/8-15/16-21
Ortho Tri-Cyclen Low	O/W/B	EE	25	1-21	NGM	180/215/250	1-7/8-15/16-21
Triphasil/Tri-Levlen/ Trivora/Enpresse	W/BE/WAT/BA	EE	30/40/30	1-6/7-11/ 12-21	LNG	50/75/125	1-6/7-11/12-21
Ortho Novum 7/7/7 / Nortrel	O/BA	EE	35	1-21	NET	500/750/1000	1-7/5-16/17-21
Tri-Norinyl	WAT	EE	35	1-21	NET	500/1000/500	1-7/8-16/17-21
PROGESTIN ONLY							
Micronor (28 day)/Errin/Jolivet	O/BA/WAT				NET	350	
Nor-QD (28 or 42 day)/Camila	R/BA				NET	350	
Ovrette (28 day)	W				NG	75	
Aygestin	L				NETA	5000	
Cycrin	W				MPA	2500/5000/10000	
Cerazette	OR				DSG	75	

EE—ethinyl estradiol; ME—mestranol; 17BE2—17-beta-estradiol; CE—conjugated estrogens; LNG—levonorgestrel; NE = NET—norethindrone; EDDA—ethynodiol diacetate; NETA—norethindrone acetate; NG—norgestrel; NGM—norgestimate; D-AcylNGM—norgestromin; MPA—medroxy progesterone acetate; DSG—desogestrel; 3-Keto-DSG—etonorgestrel(ENG); DSP—drospirenone, GEST—Gestodene

Metabolism

- 1) ME→EE active metabolite
- 2) EDDA & NETA→NET active metabolite
- 3) 50% NG & 20% of NGM→LNG
- 4) NGM→Dac/NGM
- 5) DSG→3 Keto DESO(ENG) – Like LNG only one carbon different
- 6) EE, CE, NET, DSP, MPA, ENG, D-acetyl NGM, and LNG are all active and do not need metabolism to work

Progestin with Estrogen activity

Weak EDDA & NETA with 10% EE2 activity (1000 mcg NETA=5 mcg EE2)

T ½ drug half life

NET = 4 - 13 range or 7 hours NGM = 12 – 30 range or 12 hours DSP = 30 hours
 Lng = 11 - 45 range or 15 hours DES = 14 – 38 range or 12 hours MPA = 30 hours

Progestin binding – rabbit endometrium

Gestodene (not in U.S.A.) > Deso & Lng > NGM > NET & EDDA

Potency (dose needed for ovulation suppression and as potency increases less drug is needed)

GEST> Deso & Lng > NGM > NET & EDDA > DSP & MPA

Androgen binding at doses 50x ovulation suppression doses

DHT = 1.0 NGM = .003 MPA, DSP, NET = none Lng = 0.2

Mineralcorticoid activity

DSP potassium monitoring is needed and hepatic, cardiac, renal disease, or chronic use of NSAIDS contraindicated.

Spermicide

What is a Spermicide?

By definition, a spermicide is a chemical that kills sperm. Nonoxynol-9, or N9, is the most common spermicide, a substance that can destroy sperm. N9 is a chemical detergent that breaks the cell membranes of the sperm. Unfortunately, N9 can also irritate and disrupt the vaginal epithelium. Spermicide strength varies greatly and extensive tests by the manufacturers are currently not required. The dose of N9 needed to destroy sperm is thought to be around 100 to 150 mg. A large NIH comparative trial found failure rates of 10-22% over 6 months and concluded N9 products under 100mg should not be used (Obstet Gynecol 2004; 103: 430-9). An earlier study of women using a 70mg N9 product multiple times a day did not appear to reduce pregnancy rates and these women also had much higher rates of HIV acquisition. Consequently, clients should be advised that high dose products, like the 1000mg sponge, or repeated dosing causes vaginal irritation and even mucosal ulceration. There is also concern that N9 can react with latex condoms and cause more release of the latex proteins, which could then increase the risk of latex allergy. The use of the spermicide N9 should not be promoted to reduce the transmission of bacteria or viruses that cause STD's and in fact the use of N9 may increase these conditions. Condoms with N9 are not recommended and do not add benefit.

History and Examination

Initial Clinic Visit

The standard medical history is reviewed and enlarged upon as clinically appropriate by the clinician. The minimum required physical examination is performed and recorded, and if needed, additional examination done as indicated by the history. Minimum laboratory tests are obtained and reviewed. Inform the client about male and female condoms as superior alternatives. Advise the client about emergency contraception and for most clients a package of EC should be prescribed and dispensed prophylactically.

Subsequent Clinic Visits

The client should return if they have problems or as needed for supplies. At every visit, document alternative superior contraceptives were offered to the client. An annual exam should be offered yearly.

Contraindications and Precautions

- Allergy to spermicide or ingredients in base.
- Recurrent urinary tract infections.
- The failure rate for spermicide alone is very high with 28% of women experiencing a pregnancy within the first year of use.
- Spermicides cause irritation and increase mucosal damage and potentially facilitate the transmission of blood borne viral infections like HIV and Hepatitis.
- Should never be used in the rectum.
- The sponge is significantly less effective than the diaphragm with spermicide with 17-24% of women pregnant at one year of sponge use and only 10-12% of diaphragm users (*Contraception* 2003; 67: 15-18).

Benefits

- Available without prescription
- Non-hormonal
- Reversible
- Controlled by the woman

Possible Side Effects

- **Allergy to spermicide:** If a rash, women may use cortisone cream (ointment is better as there is no alcohol as in creams) on her vulva for a few days. She could try a different type (cream versus gel or film versus suppository), different brand, or different spermicide (octoxynol versus nonoxynol-9). Remember some of these products cannot be used with latex condoms as they may weaken and cause breakage of the condom. One possibility is to rinse off the outside of the vulva with water, not a douche but with fingers, and then in six hours remove the spermicide from the vagina. However, remind the client that current spermicide chemicals act as detergents and it is difficult for it to work unless it has irritant properties. Lastly, it may be best for the client to consider a different contraceptive method.
- **Increased vaginal infections:** Examine for yeast, bacterial vaginosis, etc. The client can try using condoms as well as spermicides. If problems persist, the client may need to change methods.
- **Increased urinary tract infection:** Advise women to drink fluids, to urinate both before and after intercourse, and to wipe from front to back with toilet paper use.

Dispensing/Patient Education

- Spermicide products are bought over the counter and vary from 60mg to 1000mg of N9 per application.
- Routinely give spermicide cream or jelly with a diaphragm or a cervical cap as part of the combination method. Also provide an applicator to add additional spermicide. For women using the method alone educate about the lower effectiveness and suggest a higher dosage of at least 150mg of N9 per act of intercourse. Repeat foam application with each act of intercourse.
- When using suppositories or film, the couple needs to wait 15 minutes after insertion for the suppository or film to dissolve before sexual intercourse. Foams, creams and jellies are usually effective immediately.
- The Today brand of sponge with 1000mg N9 can be bought in Canada and is left in place for repeated acts of intercourse over 24 hours. Women need to be advised of the possible risk of toxic shock syndrome, difficult removal, and risk of vaginal irritation from the high dose of N9.
- Canada also sells another type of sponge called Protect Aid, which uses F-5 Gel (contains N9, benzalkonium chloride, and sodium cholate), which permeates a polyurethane foam disc.
- Both sponges use a polyurethane foam material with a metabisulfite or sulfur like material for a preservative. The sponge needs to be left in place for at least 6 hours after the last act of intercourse to provide efficacy. Either sponge can be used for repeated acts of intercourse but for only 12 hours if the Protect Aid brand and up to 24 hours if the Today sponge.
- The client needs to read the package instructions carefully.
- If the woman is seeking a sexual lubricant then a N9 or spermicide product is not necessary and has not been shown to be beneficial.

Sterilization

Sterilization is permanent contraception usually accomplished by a surgical procedure. In men, the vas deferens are interrupted and in women, the fallopian tubes. Hormonal production can continue, in women with menstrual cycles unaffected, and in men, ejaculation is unchanged. In women, ovulation continues but due to tubal interruption fertilization by sperm is greatly reduced. The failure rate for vasectomy is less than 1 in 1000 if the semen sample 12 weeks after the surgery has no sperm in the ejaculate. A recent study suggests half of vasectomy failures happen in the first 3 months (Obstet Gynecol 2004; 103: 848-50). The 10 year failure rate for female sterilization is 0.8% for postpartum partial salpingectomy and can be as high as 2% for interval laparoscopic methods involving cauterization, clips, or bands. Women under the age of 28 have a higher rate of failure and 15% to 40% incidence of regret, but only 1% actually seek and obtain reversal. In the U.S., over 1 out of 4 couples seek sterilization, with approximately 2 women sterilized for every man. An excellent review of sterilization can be found in the September 2003 ACOG Practice Bulletin No. 46.

Consent

The consent must be signed by both the patient and the provider obtaining the consent at least 30 days prior to performing a tubal ligation (although there is an exception if delivery occurs before 37 weeks) or a vasectomy. Any woman who is considering postpartum tubal ligation should be thoroughly counseled about this option during pregnancy and sign the consent as soon as their decision has been made. Consent forms for sterilization, as well as patient education brochures, can be ordered using the [Office of Population Affairs Publications Clearinghouse Order Form](#). The State has a document describing the consent process and this is an important resource ([Sterilization Consent Procedure](#)). [Instructions for Take Charge Sterilization Referral and Billing Information Cover Letter](#) should be used. Providers can also provide the [Female Sterilization Referral List](#) or [Vasectomy Referral List](#) but these lists are only representative of the local providers and do not imply endorsement. All providers on the list agreed at the time of the data collection to provide Medicaid services.

Counseling for sterilization should include:

- Explore other contraceptive methods including long term reversible methods such as pills, injections, implants, and the IUD.
- Explain that sterilization must be considered permanent and irreversible with 15% regret and 40% if under age 30. Even with very expensive surgery to put the vas deferens or fallopian tubes back together, fertility (ability to get pregnant) can be less than 50%.
- Explain that the female sterilization failure rate is approximately 2% or 2 out of 100 women pregnancies over 10 years
- Discuss the possibility of future ectopic pregnancies (one third of all failures) with female sterilization and the need to seek care promptly if she suspects pregnancy after having had a tubal ligation performed
- Describe the surgical procedure:
 - Postpartum tubal ligation is usually performed the day after a vaginal delivery. A small incision is made at the umbilicus. Each tube is located, the middle portion removed,

and the separate ends tied. This procedure can also be performed at the same time as a Cesarean delivery. Postpartum tubal ligation requires anesthesia, usually spinal or epidural.

- Interval tubal ligation is performed more than 6 weeks after delivery, using a laparoscope to visualize the tubes. The tubes are cauterized or occluded with a clip or ring. This procedure usually requires general anesthesia and takes 30 to 60 minutes. Women go home that day.
- It is rare but approximately 4 deaths occur per 100,000 sterilization procedures.
- A new device, Essure, was FDA approved in 2002. These metal and dacron coils can be placed using hysteroscopy under local anesthesia. But 10% of the time the surgery can not be done, 4% of women need to wait an additional 3 months or have the procedure repeated, and all women getting these coils placed need a hysterosalpingogram to verify tubal scarring was successful (Obstet Gynecol 2003: 102: 59-67).
- If a vasectomy, the procedure is done in the office under local anesthesia with the skin over the scrotum opened and the vas deferens located for ligation. After a vasectomy, clients will still need a back-up contraceptive method until the sperm test is negative (can be up to 3 months).
- A vasectomy or tubal ligation do not reduce the risk of STDs, a condom is still needed for protection.
- Vasectomy does not increase the risk of prostate cancer even after 25 years according to a large population – based age control study (JAMA 2002; 287: 3110-3115),

Post Vasectomy Semen Evaluation

If a vasectomy is done by PHSKC then use the [Vasectomy Information and Consent Form](#). A man presenting after a vasectomy should be advised that a semen sample should be checked for the presence of sperm first at 6 to 8 weeks and then 4 weeks later or with a single negative specimen 12 weeks later was found to be the best predictor of efficacy. The man should have at least 12 to 20 ejaculations following the procedure before the first assessment to ensure the clearing of the sperm already in the vas deferens tract. The sample is collected in a sterile container and should be evaluated as soon after ejaculation as reasonable to best detect motile or live sperm (which would be worrisome for an incomplete transection of the vas deferens or a fistula).

The semen sample should be well-mixed and placed directly on a glass slide with coverslip. Examine for presence of spermatozoa under low then high power, covering all areas of the coverslip and report as number of spermatozoa seen per hpf. Remark on absence or presence of sperm and if motility is present.

Any man testing positive for any spermatozoa should be advised he is not infertile and needs to continue alternative contraception and to bring another semen sample in 4 weeks (advise ejaculations at least 2 to 3 times per week). A man testing positive at the second test should be referred back to the surgeon for consideration of a repeat vasectomy procedure.

T ransdermal Contraceptive Patch

Overview

The FDA approved the Ortho Evra™ contraceptive patch November 2001. The Ortho Evra™ transdermal contraceptive system (TCS is the abbreviation) or patch contains both estrogen and progestin. The patch is applied to the skin with a new patch each week for a total of 21 days followed by a patch free week. Because this patch is the only patch available on the US market for the remainder of the chapter when the word patch is used it will refer to the Ortho Evra™ patch or the patch.

The patch is 20 cm² (roughly 2 inches by 2 inches) and consists of 3 layers: an outer flesh colored protective polyester layer, a medicated adhesive middle layer, and a clear polyester liner sheet which is removed prior to application. The patch releases 20 mcg of ethinyl estradiol and 150 mcg of norelgestromin (also known as 17-deacetylnorgestimate) daily. This prevents ovulation and is the primary contraceptive mechanism. Absorption of the estrogen is almost 100% and serum estrogen levels are actually very similar to that of a 30-35 mcg orally administered COC pill. This might explain why the reported patch side-effects may be estrogenic in nature for some women. As of 2004 approximately 4 million American women from 8/2002 to 9/2004 had used the patch and there were at least 8 deaths reported in young healthy women, primarily from stroke or thrombosis. While this risk is not greater than a COC pill it is likely the adverse events are underreported. Because this is still a relatively new method if any patient in the PHSKC has a blood clot while using the patch this should be reported with the FDA MedWatch form.

The patch is to be placed on day one of the cycle and then replaced with a new patch every 7 days for a total of 3 weeks. Then a patch free week induces withdrawal bleeding. Because of the higher estrogen levels and the relatively weak progestin ratio this product should not be used for menstrual suppression or continuously. It is unknown if endometrial hyperplasia can be prevented or if extended use would induce hypercoagulability not seen with cyclic use, besides not being FDA approved for extended use. The patch hormones will accumulate within the skin and the hormone levels are higher in the third compared to the first week of use so it may be important to have the patch free week.

The patch is applied to one of four sites: buttock, lower abdomen, upper outer arm, or upper torso. The patch should never be applied to the genitals or breasts. The patch site should be rotated and a new patch needs to be applied to a new site. Oils, creams, or cosmetics should not be applied to or around the patch with 3% of patches partially lifting and 2% of patches falling off and needing replacement during studies. Once the patch has adhered the woman may shower, bathe, swim, and use a hot tub. Approximately 2.6% of users quit because of problems with the patch and 20% overall reported some site reaction at some time during the studies.

User compliance with the patch was 90% in the studies, which is better than with pill use. Overall fewer pregnancies happened in the patch users but statistically it was not significant. The method failure rate was similar to the OCP during the clinical trials with less than 1% of women experiencing a pregnancy with perfect use and less than 2% failure overall. However many of these failures or pregnancies were in obese women and women weighing 90 Kg (198 pounds) or more had an 8% failure rate while using the patch (Smallwood GH et al. Efficacy and safety of a transdermal contraceptive system. Obstet Gynecol 2001;98:799-805). The FDA noted this when the patch was approved and although the studies are still inconclusive it is prudent to recommend the patch to women weighing more than 90 kg only with

additional consent until there are more reassuring findings.

Benefits

- The same benefits as the OCP including a reduction in menstrual flow, anemia, and ovarian cysts for example. Although compared to Triphasil OCP in a RCT the patch users reported more dysmenorrhea (Audet MC et al. Evaluation of contraceptive efficacy and cycle control of a transdermal contraceptive patch vs an oral contraceptive. JAMA 2001;285:2347-2354).
- Do not have to remember a pill every day.
- Once the patch is in place then nothing needs to be done for 7 days.
- Increased method compliance compared to the birth control pill especially in young women.
- The contraceptive steroids are absorbed from the skin and this delivery system avoids the gastrointestinal tract and first pass hepatic metabolism seen with oral administration. The patch delivers the steroids continuously so the peaks and troughs with oral administration are not present.

Absolute Contraindications

For women with any of the following, methods with estrogen like the patch should not be prescribed.

- Women with a [personal history](#) of a blood clot or **thrombotic event**, deep vein thrombosis, pulmonary embolism, cerebrovascular accident, myocardial infarction, or coronary artery disease.
- **Known pregnancy**
- Known **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of hormones could worsen their prognosis.
- **Active hepatitis with jaundice**, liver failure, hepatic adenoma, and hepatic malignancy
- Women **35 or older who smoke** tobacco. Women smokers aged 35 to 44 may only use 20 mcg pills or the ring if they sign the [Birth Control Method Specific Informed Consent Form](#) and are counseled to reduce to ≤15 cigarettes a day. Do not give the patch to these women, the estrogen exposure is greater.
- A girl that has **never had a menses**, since estrogen will stop her bone growth. Once menarche is reached, even one menses, then endogenous estrogen levels have begun.
- **Allergy** to adhesives or other transdermal delivery systems. It is very probable the contraceptive patch would contain some of the same ingredients as other adhesives.

Relative Contraindications

For women with any of the following, methods containing estrogen like the patch should not be prescribed unless the client insists this is the only method she will use. She must then sign the [Birth Control Method Specific Informed Consent Form](#) and the provider must document the discussion about alternative methods offered and the client accepting the risk from estrogen. In addition, the 20 mcg EE pill dose or the ring should be prescribed unless documented intolerance and the patient understands her risk may be increased with increased estrogen dose from the patch.

- Women with more than one **first degree relative with a history of a thrombosis** that occurred spontaneously (no injury or pregnancy, and especially if clotting event when young) may have inherited a thrombophilia. If the woman wanting an estrogen method who has **never taken estrogen or had a pregnancy** then this may be her first exposure to sustained estrogen and this could induce a clot. Remember many women could have an inherited decrease in the ability to stop clotting and yet they may never have a problem. One calculation published by an Italian research group stated that COC pills would have to be withheld from 90,000 women to prevent one DVT. Since only 1% of DVTs cause death, it makes no sense to withhold COC pills to healthy young women for just a family history. A study of women with blood clots found very few had a family history which suggests family history

will not predict many events. Even if these women with a family history had the \$300 worth of tests done to see if they inherited the gene, half the time the tests will be negative and she could still have a hereditary propensity to clot. Use the [Birth Control Method Specific Informed Consent Form](#) if family history and no prior estrogen exposure to document she was told of the unknown and probably very small risk of blood clots when using estrogen. To put the risk of getting a blood clot in perspective, if one followed 100,000 healthy young women for one year, 5 of them would get a DVT (and only 1% are fatal). If you then gave all these women COC pills, then 10-30 of them would get a DVT during the year, and if the person had half of the gene (heterozygote) for a clotting problem (Leiden Factor) then the rate would be three times that of normal women with around 30 to 90 of women getting a blood clot during that year which is the same as if the women were all pregnant for that year. If the woman had inherited both genes (homozygote) then her risk for a blood clot is very high and if this is known then these women should not use estrogen. You should refer for familial thrombophilia evaluation prior to estrogen use if client has two first-degree relatives with clots especially if an affected relative can also attend the visit, to the Hematology Clinic at Harborview Medical Center (see [Information About Referral to Harborview Medical Center Handout](#)).

- Known or suspected **migraine headaches**, which may be worsened. If frequent vascular symptoms like blindness or numbness then refer to neurology and do not prescribe the patch. If migraines with vascular symptoms that are very rare or in the distant past, give only 3 cycles and evaluate for exacerbation. There have been reports of strokes and deaths in young women with patch use and this risk is increased in women with a history of migraines. If headaches begin or worsen during patch use then stop the patch.
- **Chronic active hepatitis** usually from a viral etiology like hepatitis B or C or a history of jaundice during pregnancy or chronic liver disease like Gilbert's Disease. Question the client and if she reports jaundice or documented hepatitis with abnormal liver enzymes within past three years then send a liver panel. If she has had no jaundice or documentation of elevated liver enzymes in past three years, then the prescription can be begun with one package on the same day as the baseline liver enzyme panel. If the liver enzymes on the baseline lab test are double the normal values then plan to repeat liver panel in 3 months and after one year of use. Refuse a refill if enzymes have worsened until consultation with Family Planning Medical Director. If the enzymes were more than double the normal value, a woman has impaired liver function and her liver cannot metabolize the estrogen. Estrogen is not toxic to the liver and it will not worsen liver function, but a low dose estrogen exposure will become a high dose exposure because metabolism is impaired and she is then exposed to the risks of thrombosis. The process of metabolizing the estrogen could also possibly worsen her liver function and ability to metabolize other medications.
- **Hepatic adenoma**. The old high dose pills used to be associated with benign hepatic adenomas, which could sometimes distend, enlarge the liver, and rupture causing bleeding. Recent literature states the low dose pills have not had this problem but any estrogen containing prescription label will contain this warning. If someone has a known diagnosis of hepatic adenoma, estrogen is contraindicated.
- Suspected **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of hormonal products could worsen their prognosis.
- Suspected **pregnancy**, although there is no evidence of teratogenesis in women who inadvertently took low dose oral contraceptives during the first four months of pregnancy.
- Women with **diabetes and microvascular disease** such as retinal or renal damage proven or

suspected is an absolute contraindication to estrogen use. Retinal vessel damage is not usually seen till after 10 years of insulin use and is very rare in non-insulin users. Diabetic women on insulin are

followed by primary care providers and should have regular eye, renal and lipid evaluations with these providers. Estrogen and progestin use may change slightly the insulin dose needed but it is safe, will not worsen their diabetes, and is preferable to pregnancy.

- Women with **hypertension**, even if treated, have an increased cardiovascular risk with the use of estrogen. Consider changing to a method with no estrogen, or if unacceptable, the 20 mcg estrogen pill or ring with the [Birth Control Method Specific Informed Consent Form](#). If the blood pressure remains elevated or worsens after 3 months, then COC pill or ring use should cease. Do not prescribe the patch to women with hypertension. Estrogen can increase blood pressure and fluid retention and can interfere with hypertension medications and treatment.
- In women with **epilepsy**, the patch may be less effective due to **seizure medication** use. This includes carbamazepine, primidone, phenytoin (Dilantin), and phenobarbital. The Family Planning Program will not be prescribing 50 mcg estrogen dose pills because estrogen absorption and metabolism is very different in individual women. The woman on a high dose estrogen pill is exposed to potentially higher thrombotic risks. Estrogen also lowers the seizure threshold in the brain and can increase the number of seizures. The IUD or DMPA injection are the preferred hormonal contraceptive in women on antiepileptic medications. There have been no reports of the use of the patch in women taking these medications and it is a labeled contraindication. While it is possible the patch could provide a steady state of contraceptive hormones and thus be effective and not interfere with the seizure medications, it is also possible the estrogen levels could interfere with seizure suppression although natural menstrual cycles or pregnancy could be worse. Consult the Family Planning Medical Director, use the [Birth Control Method Specific Informed Consent Form](#), and if possible consult and follow the patient with her primary provider managing her seizure disorder.
- Use of **rifampin** for tuberculosis increases the metabolism of estrogen and will make the method less effective. During short-term therapy such as meningitis prophylaxis, continue the patch but use a back-up method also as rifampin use has been associated with many OCP failures;
- **Immobility** such as need for a wheelchair, non-weight-bearing long leg cast, major surgery defined as causing immobility for more than two days or a long surgery, greater than two hours, planned, etc., which will predispose to thrombosis. Need to discontinue patch use 4 weeks prior.
- **Any patient with acute or recent serious illness or chronic serious cardiovascular, vascular, or renal disorders** which may be aggravated by thrombosis or fluid retention such as congestive heart failure, renal dialysis, artificial heart valve for which the client is on anticoagulants, Lupus, Kawasaki disease with prior CAD, and many more conditions. If a patient has a serious medical condition it is often prudent to consult the Family Planning Medical Director prior to prescribing an estrogen containing method because there may indeed be a risk not discussed in the guidelines.
- **Hydatidiform mole or choriocarcinoma** currently being treated, with elevated serum HCG levels, should not have COC pills and perhaps not use the patch since similar hormonal medication until the HCG levels are normal. A large case study of women with choriocarcinoma found that women given COC pills while their HCG levels were elevated were significantly more likely to require chemotherapy than those that did not use exogenous hormones until the HCG level had returned to normal (which would be close to zero).

- **Chronic skin or dermal conditions** (for example eczema or psoriasis). It is possible the adhesive product could exacerbate or trigger a rash. Although it is unlikely to be life threatening the chart should still contain a documented warning to the client that the method relies on adhesion to deliver the contraceptive steroids and studies have not been done in women with chronic skin conditions. Approximately 1-2% of women using the patch will report some hyperpigmentation of the skin where patch use has been and this may not be reversible.
- **Obesity.** A weight greater than 90 kg or 198 pounds is a relative contraindication to the method due to decreased effectiveness (8% failure versus 1% failure). The 3319 women during 22,155 patch cycles or up to 1 year of patch use were used to determine efficacy resulted in 15 pregnancies. Five of these were in the 3% of women weighing 90 kg or more. The other 10 pregnancies were evenly distributed over body weights below 90 kg including 1 in women 80-84 kg and 1 in women 85-89 kg. Therefore, it is a small possibility women close to 90 kg might even have a small risk of failure but it is unknown.
- **Chronic headaches.** Have the woman keep a diary of her headaches using the [Headache Diary](#) and if she notices the headaches are worse during patch use then consider stopping patch use however if the headaches appear to only happen in the patch free interval then consider estrogen withdrawal etiology and consider switching to a 20 mcg dose OCP for continuous use and consult the menstrual cycle suppression chapter. Do not recommend or prescribe the patch for continuous use.

Precautions

Women with the following may be given a patch prescription if, in the judgment of the clinician, an alternative method of contraception would not be acceptable to the client or would increase the risk of an unwanted pregnancy.

- **Undiagnosed vaginal bleeding** until diagnosis is established and managed. Although often COC pills or the patch could be used to regulate irregular menses. If the COC pills regulate the menses there is usually no further need for diagnostic tests. A 3 to 6 month trial of COC pills or patch can be a diagnostic maneuver, proving that the history of irregular menses was most likely caused by lack of regular ovulation.
- **Lactation:** The amount and possibly the quality of milk will be lessened with the use of estrogen especially in the first 6 months post partum. If weaning is desired, COC pills or the patch may be used to decrease the flow of milk. A progestin-only hormonal contraceptive is preferred and can actually increase the amount of milk produced. If lactation is well established and greater than six months, then a change to COC pills is possible but if there are problems, change back to POP. Use of the patch in lactation has not been studied and is not recommended because of the relatively high estrogen levels induced with patch use.
- **Active gall bladder disease.** Estrogen use can worsen stone formation and dilation of the bile ducts. If they have had their gallbladder removed then there is no risk with patch use.
- **Chronic yeast vaginitis.** This may possibly be worsened by cyclic estrogen use. There is a study that found DMPA use, which reduces estrogen levels, decreased the number of yeast infections.
- Use of **oral antibiotics** in particular metronidazole, amoxicillin, ampicillin, and tetracycline, have been associated with case reports of COC pill failure while taking these and other antibiotics. The mechanism for the failure is probably a change in the gut flora so the enterohepatic absorption and circulation of the estrogen and progesterone change resulting in subtherapeutic levels. It is unknown

at this time if the patch because it delivers the hormones via the dermis would be unaffected by antibiotic use and at this time it is prudent to give the same advice as given with OCP use. The most conservative advice is to use a back-up method for the duration of antibiotic use (see [OCPs and Antibiotic Use Handout](#)) although the current Contraceptive Technology edition does not think this is necessary with COC pill use, POP users because of lower progestin dose should consider a back-up method. If the woman is on chronic, daily low dose antibiotics (like acne suppression with tetracycline or nightly Septra for pyelonephritis prevention) use the Birth Control Method Specific Informed Consent Form advising the pill method may not be as effective as in a non-antibiotic user and consider continuous and not cyclic use. There was a small study of 24 women using the patch with tetracycline 500 mg every 6 hours for 1 week and the serum levels of the hormones were not significantly changed (not published yet so actual data not seen). So it is possible the patch may be less vulnerable to antibiotic use although remember it is likely failures on antibiotics are related to

individuals. Some women have the problem because of their individual hepatic metabolic enzyme activity and others may not. If no break through bleeding or diarrhea then most likely there are effective hormone levels.

- Consult the OCP guidelines if other chronic medications as some would be contraindications to patch use and those reference tables are not duplicated here.

History and Consent

The standard medical history is reviewed by the clinician to confirm absence of absolute and relative contraindications. Counseling should be provided to ascertain ability to comply with placing and removing the patch. If contraindications do exist then document other methods discussed, patient's decision to not use other methods, and if appropriate sign the Birth Control Method Specific Informed Consent Form. If the client has signed this consent form then she needs to sign it every year when she is given a prescription for the patch. Her risk profile may change and there needs to be documentation that she was offered other methods every year and continues to choose the patch.

Examination

Baseline blood pressure, weight, and pregnancy testing (if needed) should be performed prior to prescription. Although there is no increase in the risk of breast cancer with patch use annual breast exam should be performed to emphasize the importance of early detection and screening. There is a small possibility that a rare form of cervical cancer, adenocarcinoma, is increased in COC pill users due to the estrogen proliferative effect on cervical ectopy or glandular epithelium of the cervix, and for this reason annual cervical cytology should be offered if indicated by her sexual and cervical cytology history (consult the cervical cancer screening guidelines). There is an option of delaying the pelvic exam and those guidelines should be consulted. Progestin thickens the cervical mucous and atrophies the endometrium and this can decrease the ascent of bacteria to the upper genital tract, thus one can find asymptomatic chlamydial infections in OCP users. All patch users should be offered STD screening as per the PHSKC STD guidelines.

Prescribing the patch

Prescription medication can usually only be dispensed by pharmacies. Washington pharmacy code allows dispensing of contraceptives, and only contraceptives, by non-pharmacy persons at Family Planning Clinics. However the patch cannot be dispensed unless there is a valid and current prescription. A prescription can only be written or given orally by a provider with prescribing authority.

- **First time patch users** can only get an initial supply of 3 cycles. This 3 month revisit is to ask about complaints or difficulties with patch use and to measure the weight and the blood pressure. These are

to be recorded by a clinic nurse and any significant problems evaluated by the clinician. Make sure the client is using the patch correctly. Use the [Female Contraceptive Visit Form](#) or similar note at visit. She can then be given another 4 months supply.

When to begin patch use

Patch use should ordinarily be **started on the first day of the menses**. A first menstrual day start will induce faster and more complete ovarian suppression and for this reason no additional back up method is recommended by the labeling if begun correctly.

- Women starting the patch **after the 5th day of menses** should use added protection for 7 days. If starting on the first day of menses then no additional protection is needed for that cycle. Women **switching** from another hormonal method will be protected from the beginning of patch use if no longer than a 7 day interval from the last pill or ring or within the effective time of an injection. To alter the day of the week for patch administration may require the use of a back up method until the preferred day.
- Patch use may be started **21 days post partum** in women choosing not to breast feed (estrogen can stop lactation) or on the **day of an abortion** for any pregnancy **less than the late second trimester**. After 24 or more weeks gestation, do not start estrogen use until three weeks post-delivery or abortion to minimize the risk of increased thrombosis post delivery. By 2 to 3 weeks post partum, 30% of non-breast feeding women will ovulate and could potentially get pregnant.
- **Same Day Start/Restart** may be done if the patient understands and consents. This means the first patch is placed the day of the clinic visit and can even be done there in the clinic with teaching. This may be appropriate in women taking ECP, or who has recently been on pills and missed more than 3 days of pills, or who has had a history of irregular menses and waiting until menses will increase the risk of pregnancy. It may also be appropriate for women whom the provider thinks may benefit from actual patch use teaching. Documentation of a negative HCG test is required. Consider if the client also needs an EC prescription because regular dose OCPs will not act as an EC. The client must understand the need for a backup method for 7 days and that a pregnancy test should be done in 4 weeks, especially if no bleeding. Provide counseling to the client that beginning a hormonal method midcycle can result in increased break-through bleeding and if it is worrisome to the patient, it may be better to wait until the next menses. But in some women, like prior DMPA users, beginning a hormonal method when the client wishes to start is better than waiting for a menses. After 3 months of patch use typically the cycles are regulated and the same day start will have no lasting effect.

How to use the patch

The patch may be applied to one of 4 sites, absorption equivalent, on the skin: the lower abdomen, upper outer arm, upper torso, or buttock. The patch cannot be applied to the genital area or the breast (not known if local tissue would be effected by the high hormone levels). The patch is also to be applied to clean dry skin free of lotion or oils although no special preparation should be done. The patch should be held tightly to the skin for 10 seconds to help it adhere tightly. The patch is worn for 7 days although contraceptive levels have been proven to continue up to 48 hours if patch removal is delayed or a new patch is not applied directly following removal of the prior patch. In other words, as long as a new patch is placed within 2 days ovarian suppression should continue. Use of a single patch for more than 9 days has not been studied (very likely it will be ineffective as the levels had dropped quite low by day 9 of use) and the woman needs a backup method for 7 days and consider pregnancy testing at revisit if this reported.

The patch is to be peeled off and sticky side stuck to sticky side so hormone releasing surface is covered and can not leak into landfill and discarded in the trash not the toilet. If there is adhesive left on the skin

mineral oil can be used to remove it, being careful to apply the new patch to only clean and dry skin. A new patch is then directly applied to a new but adjacent site or perhaps a new site entirely.

If the patch does not adhere or partially detaches the entire patch must be removed. Adding tape to the patch is not an option, the drug delivery system requires the adhesive be tightly adhered over the entire patch surface to deliver the drug. In studies approximately 3% partially detached and 2% of patches had to be replaced. If a patient consistently requires additional patches then a different method should be considered. Tests were done with patch use with exercise, perspiration, hot tubs, saunas, humid environments, and cool water immersion and the delivery system was unaffected and fewer than 4% of patches detached and needed replacement. Women cannot tattoo or color the patches as this could change drug delivery.

The patch needs to be replaced every 7 days with a new patch to maintain contraception. Hormone levels drop to zero within 1 week following patch removal hence the need for a new patch after the patch free week to maintain contraception. After 3 weeks or 3 patches the woman is to have a patch free week to allow withdrawal bleeding. If a patch was accidentally left on for more than 7 days the week before the period week then either the patch free week should be only 4 days or a new patch used to skip that period week. There is no data or studies regarding extended cycles or menstrual suppression with the patch and it is possible continuous use could lead to endometrial proliferation since the ratio of the estrogen to progestin with the patch favors estrogen..

Getting An Extra Patch

Because the patch can fall off or need to be emergently replaced, women need to have access to extra patches. A woman getting her supplies from PHSKC should get 84 day prescriptions (#12 patches with 3 refills) and be advised to always make sure she has at least one patch in addition to one she is using and not to wait to get a refill only when she is using her last patch. If the patch prescription has to be filled at an outside pharmacy, then write two prescriptions, one for the year's supply and one for an extra patch. This extra patch prescription can be kept on file at that pharmacy or kept by the patient in the event of needing an urgent refill at any available pharmacy. She would go to the pharmacy with this extra patch prescription. If she pays for that patch, she can then submit this bill directly with the extra patch certificate (in the box with the extra patch) to the Ortho Evra extra patch program (www.orthoevra.com or 1-800-682-6532). If this extra patch is paid for by Medicaid insurance then no rebate can be requested.

Product Brochure

The manufacturer's patient product labeling is to be given to the client each time the patch is dispensed.

Possible Side Effects

- **Nausea.** The nausea is not the result of a local effect on the stomach but because the estrogen is working on the brain to cause nausea. For this reason even women using the patch may experience nausea from estrogen. In a comparative study the women using the patch reported significantly more nausea than the OCP user (Triphasil was being used in the study and that OCP has estrogen doses of 30 to 40 mcg). It is possible the constant sustained estrogen levels result in more estrogenic side effects like nausea and breast tenderness although with continued use these should subside. Placing the patch on the abdomen may reduce the nausea side effect according to the patch company.
- **Weight Gain.** In studies of large numbers of women OCPs did not significantly increase the weight of the population however individual women may respond differently to hormone use. Weight gain is usually from increased food consumption and decreased activity. In the women using the patch in the clinical trials the weight gain was similar to that as measured in pill users, less than 2 pounds after one year (which was similar to the weight gain measured in placebo patch users in a small study).

- **Site reactions.** In the studies 20% of women reported some site redness or irritation although only 2% of women stopped using the patch because of problems with their skin due to the patch. It was very common for the patch site to be slightly red for an hour after patch removal. The patch sites were studied using ultraviolet light and the company states the use of the patch was not associated with phototoxicity or photo allergy. If use of the patch consistently leaves a rash or skin lesion which persists the woman might consider a different method because there is nothing that can be done to prevent a dermal reaction with future use. While short term treatment with a mild hydrocortisone cream might be offered to clients presenting with a patch related inflammation, if repeated rashes happen the method must be discontinued. Approximately 1-2% of women using the patch report some hyperpigmentation of the skin from patch use and this may not be reversible and would likely continue to occur with ongoing patch use.
- **Breakthrough Bleeding (BTB) or Spotting.** BTB is when the woman reports having bleeding when using the patch instead of during the patch free week or scheduled withdrawal bleeding. BTB is defined as enough bleeding to need a hygiene product like pads or tampons and spotting is when no protection was needed.

First 6 months of patch use:

- **Reassure client** this is very common when first beginning hormonal methods and is often because the uterine lining is shrinking and shedding under hormonal influence. In the first 2 months of patch use around 20% of women had BTB, twice what was reported by the OCP users in the comparative study. But after 2 months the rates were similar.
- Use the **Menstrual Calendar Reminder Card** to help patients track their bleeding and spotting.
- Be certain that the patch is being used as scheduled as a drop in the hormonal levels can worsen BTB and spotting. If the woman is **overweight** consider method failure and obtain a pregnancy test and if negative consider the hormone levels may not be adequate for endometrial suppression although patch study data did not analyze BTB in different weight categories.
- **Rule out other causes** of bleeding as appropriate by history and exam such as pregnancy, polyps, cervicitis, or other medication use.
- **Ibuprofen**, 400 to 800 mg three times daily or Naprosyn 500 mg twice a day beginning with menses, can reduce the amount of menstrual flow and the frequency of BTB or spotting. Menses or menstrual withdrawal bleeding is triggered by a drop in progesterone, which results in prostaglandin production. These chemicals then shed the endometrium by vessel spasm hence the pain and cramps.
- **Recent history of DMPA:** Injections could alter the ratio of hormone levels since DMPA is not completely cleared for 6 months after use. Because of DMPA's progestin effect on the endometrium to cause atrophy increasing estrogen may suppress BTB or spotting. Switching to a pill with a higher progestin dose may be tried since the estrogen dose in the patch is already quite high it is most likely the client needs more endometrial suppression (more progestin). Use of the patch while taking combination birth control pills is contraindicated. There are no published studies on the best formulation to transition women from DMPA to patch use.
- **Alcohol use** can also change the metabolism of estrogen so that the estrogen is metabolized

slower giving higher estrogen levels. Using alcohol daily, binge drinking or stopping alcohol consumption could trigger some transitory BTB or spotting.

- **Tobacco use** induces metabolism of estrogen making some smokers more vulnerable to breakthrough bleeding and spotting.

After 6 months of patch use:

- The endometrium should have atrophied and the most likely etiology is noncompliant patch use. For this reason **pregnancy testing** may be advised if the woman presents with bleeding complaints.
- If unexplained breakthrough bleeding occurs in women established on the patch, do an **infection check** and evaluate for other sources of bleeding before method change. If no etiology is found and the BTB or spotting persists after two cycles, **referral** may be indicated to gynecology clinic to evaluate for uterine or ovarian pathology. In women with persistent spotting with the LNG IUS it was found on ultrasound some had submucosal endometrial polyps. Although this is not a contraindication to hormone use and indeed hormones can suppress the irregular bleeding over time.
- In a randomized study of DMPA users, supplemental estrogen did not help BTB. This has not been studied in OCP or patch users, but it is unlikely to help except acutely and since estrogen causes proliferation it could be counterproductive with increased bleeding when the supplemental estrogen is stopped. Switching to a COC pill with an increased progestin dose for ongoing use might be considered.
- **Breast Tenderness.** This will usually disappear within three cycles although may be worse than that seen with OCPs. If not, lower doses of estrogen may help meaning a switch to pills or the ring. Instruct in obtaining and using proper bra. Discuss the possible role of caffeine. Some women may benefit from vitamin E 400 IU daily.
- **Headache.** Allow two to three cycles for adjustment and recommend aspirin, ibuprofen or acetaminophen. Use the **Headache Diary** to see when the headaches occur. Discontinue the patch if headaches worsen. If severe, persistent, or vascular symptoms like blindness or numbness develop, stop patch use and refer to an emergency room if acute. If the headaches are mild and associated with the patch free week, it is possible that wearing the 3rd week's patch for the 4th week, normally the patch free week, would allow a slower decline in the estrogen levels and provide less of a trigger for a headache. This is an unlabeled use of the patch and it is unknown if this would result in irregular bleeding.
- **Oligomenorrhea and Amenorrhea.** This is very uncommon with cyclic patch use (less than 2% of users over one year). Check a pregnancy test and if negative, reassure the woman although counsel to return if still no menses in the next cycle.
- **Depression and Irritability.** A low sodium diet may help if premenstrual mood changes. Hepatic metabolism of estrogen can deplete vitamin B6 (pyridoxine) so a 50 to 100 mg daily dose can be tried to see if mood improves. There is no evidence the patch has no effect on the B6 system but it is possible the higher or sustained estrogen levels could affect mood. If mood changes appear to be cyclic, then extended or continuous cycles could be tried with OCPs or ring but not the patch.
- **Increased Blood Pressure.** Repeat measurement after a brief rest in the clinic. If the increase is

sustained, consult and use the Family Planning Hypertension guidelines. If diastolic continues to be 90 mm or greater then the client cannot use the patch.

- **Acne and oily skin.** Estrogen causes an increase in hepatic production of Serum Hormone Binding Globulin (SHBG). SHBG then binds to free testosterone and androgens effectively reducing the free, which are the active, androgenic hormones. This is why all COC pills can reduce acne and hirsutism. Ortho Tricyclen, a Norgestimate triphasic, is a COC pill that has package labeling as a treatment for acne. A study compared this pill to placebo and not to another COC pill. It is very likely other COC pills also reduce acne. Probably the best pill to reduce acne would be a pill with 35 mcg of EE and low dose of a weak nonandrogenic progestin like NET (Ovcon 35). The patch has not been proven to reduce acne although acne was a rare complaint in the studies and it is unlikely to be different than the COC pill since SHBG levels were actually the same as the 30-35 mcg comparative pill users.
- **Decreased Libido.** This may be related to decreased circulating androgens. Vaginal dryness may be managed with lubricants or increased estrogen dose. A review of sexual arousal and taking a sexual history is also important.
- **Chloasma (melasma).** Hyperpigmentation areas on the face are a great cosmetic concern. Occurrence is related to sun exposure, family history, and pregnancy, and can be due to estrogen levels especially pregnancy and COC pill use. Pigmentation can be reduced by avoiding all exposure to the sun. Use of a high potency sunscreen especially on the affected areas may benefit. Bleaching agents such as hydroquinone, or tretinoin in topical creams are frequently helpful. DO NOT prescribe these, only refer. If a woman develops chloasma during pregnancy or with COC pill or patch use she is at risk to develop it with repeated estrogen use or pregnancy. Sometimes the skin changes are permanent even after discontinuation so women may choose to discontinue use of the patch or COC pills to prevent further discoloration.

Vaginal Contraceptive Ring

Overview

The FDA approved the NuvaRing™ October 2001. It is a Contraceptive Vaginal Ring (CVR is the abbreviation). Development of a vaginally administered hormonal contraceptive has been ongoing since the 1970's. The earlier rings contained only progestin delivered via a bulky silicone or latex rings which may have been worn for up to 6 months. The NuvaRing™ is very different. It contains both estrogen and progestin, the ring is made from vinyl, is very soft and flexible, is easily inserted and removed with no fitting or special placement, and is only worn for 21 days, then discarded. Because this ring is the only ring available on the US market for the remainder of the chapter when the word ring is used it will refer to the CVR, the NuvaRing™.

Transparent ethylene vinyl acetate copolymer is used to form the 54 mm (around 2 inches) diameter ring with a cross-sectional diameter of 4 mm (around 1/8th inch). The ring releases 15 mcg of ethinylestradiol and 120 mcg of etonorgestrel (also called 3-keto-desogestrel) daily. The progestin component is responsible for the contraceptive action of the ring with ovulation blocked even if the ring is kept in an extra 2 weeks. The bioavailability of the progestin is 100% but the estrogen only 50% hence serum estradiol levels are lower than any OCP but constant. There are still estrogen effects measured on SHBG and HDL levels indicating hypoestrogenism does not occur.

The method failure rate was similar to the OCP during the clinical trials with less than 1% of women experiencing a pregnancy with perfect use and 2% failure overall. Perfect use implies the woman inserts the ring within the first 5 days of menses when beginning use and then leaves the ring in place for 21 days. If the ring is removed it must be returned to the vagina within 3 hours or a back up method is needed for 7 days. Following the ring free week it is very important a new ring then be inserted to make sure no more than 7 days are ring free. Because the CVR is a low estrogen product, it can be used to suppress menses by using it without a ring free week.

With coitus the partner may be aware of the use of the ring. In studies approximately 75% of partners could feel the ring but it was very rare that the partner complained. The ring is small and soft so unlikely to be painful when touched by the penis. The amount of steroid hormones released by the ring is low and with the brief penile exposure (average coitus 4 minutes) the risk of hormone exposure is low especially since the penis is keratinized skin.

Benefits

- The same benefits as the OCP including a reduction in dysmenorrhea, menstrual flow, anemia, and ovarian cysts are likely.
- Do not have to remember a pill every day.
- Once the ring is in place then nothing needs to be done for 21 days.
- The contraceptive steroids are absorbed from the vagina and this delivery system avoids the gastrointestinal tract and first pass hepatic metabolism seen with oral administration.
- The 15 mcg of EE2 with only 50% systemic absorption means this ring is currently the lowest combination of estrogen containing contraceptive on the US market. This does not mean it can be

given to women with estrogen contraindications only that it may be better tolerated by those women sensitive to estrogen side-effects.

Absolute Contraindications

For women with any of the following, methods with estrogen like the ring should not be prescribed.

- Women with a **personal history** of a blood clot or **thrombotic event**, deep vein thrombosis, pulmonary embolism, cerebrovascular accident, myocardial infarction, or coronary artery disease.
- **Known pregnancy**
- Known **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of hormones could worsen their prognosis.
- **Active hepatitis with jaundice**, liver failure, hepatic adenoma, and hepatic malignancy
- A girl that has **never had a menses**, since estrogen will stop her bone growth. Once menarche is reached, even one menses, then endogenous estrogen levels have begun.

Relative Contraindications

For women with any of the following, methods containing estrogen like the ring should not be prescribed unless the client insists this is the only method she will use. She must then sign the [Birth Control Method Specific Informed Consent Form](#) and the provider must document the discussion about alternative methods offered and the client accepting the risk from estrogen. In addition, the 20 mcg EE pill dose or the ring should be prescribed unless documented intolerance and the patient understands her risk may be increased with increased estrogen.

- Women **35 or older who smoke** tobacco. Women smokers aged 35 to 44 may only use 20 mcg pills or the ring if they sign the **Birth Control Method Specific Informed Consent Form** and are counseled to reduce to ≤ 15 cigarettes a day.
- Women with more than one **first degree relative with a history of a thrombosis** that occurred spontaneously (no injury or pregnancy, and especially if clotting event when young) may have inherited a thrombophilia. If the woman wanting COC pills or the ring who has **never taken estrogen or had a pregnancy** then a COC pill or the ring might be her first exposure to sustained estrogen and could induce a clot. Remember many women could have an inherited decrease in the ability to stop a clot and yet they may never have a problem with a blood clot. One calculation published by an Italian research group stated that COC pills would have to be withheld from 90,000 women to prevent one DVT. Since only 1% of DVTs cause death, it makes no sense to withhold COC pills to women for just a family history. A study of women with blood clots found very few had a family history which suggests family history will not predict many events. Even if these women with a family history had the \$300 worth of tests done to see if they inherited the gene, half the time the tests will be negative and she could still have a hereditary propensity to clot. Use the **Birth Control Method Specific Informed Consent Form** if family history and no prior estrogen exposure to document she was told of the unknown and probably very small risk of blood clots when using estrogen. To put the risk of getting a blood clot in perspective, if one followed 100,000 women for one year, five of them would get a DVT (1% are fatal). If you then gave all these women COC pills, then 10 to 30 of them would get a DVT during the year, but if they were all pregnant, 60 to 100 of them would get blood clots. Increased venous thrombosis has been reported in OCP users of pills containing desogestrel. The ring contains the metabolite of desogestrel consequently these precautions apply to the ring. A recent study of

clotting found a significant increase (2x risk) in clotting in women on desogestrel compared to other progestins. For this reason, avoid desogestrel in **obese women (BMI >29)**, women who are **relatively immobile**, women with a **family history of clotting** who are to be new pill users or women with no prior estrogen exposure, or women with other risk factors for clots. You may refer for familial thrombophilia evaluation if client has two first-degree relatives with clots especially if an affected relative can also attend the visit, to the Hematology Clinic at Harborview Medical Center (see [Information About Referral to Harborview Medical Center Handout](#)).

- Known or suspected **migraine headaches**, which may be worsened. If frequent vascular symptoms like blindness or numbness then refer to neurology and do not prescribe COC pills or the ring. If migraines with vascular symptoms that are rare or in the distant past, give only 3 cycles and evaluate for exacerbation. Have the woman keep a diary of her headaches using the [Headache Diary](#) and if she notices the headaches are worse during the pill or ring free interval then consider estrogen withdrawal etiology and consider extended cycles or skipping the pill or ring free intervals. If continuous ring use is prescribed counsel and document using the menstrual suppression chapter of the guidelines being careful to document the woman was told that this is not FDA approved or labeled, could cause more ovarian suppression, to expect spotting and irregular bleeding initially, and if amenorrhea, perform HCG testing at revisit.
- **Chronic active hepatitis** usually from a viral etiology like hepatitis B or C or a history of jaundice during pregnancy or chronic liver disease like Gilbert's Disease. Question the client and if she reports jaundice or documented hepatitis with abnormal liver enzymes within past three years then send a liver panel. If she has had no jaundice or documentation of elevated liver enzymes in past three years, then the prescription can be begun with one ring on the same day as the baseline liver enzyme panel. If the liver enzymes on the baseline lab test are double the normal values then plan to repeat liver panel in 3 months and after one year of use. Refuse a refill if enzymes have worsened until consultation with Family Planning Medical Director. If the enzymes were more than double the normal value, a woman has impaired liver function and her liver cannot metabolize the estrogen. Estrogen is not toxic to the liver and it will not worsen liver function, but a low dose exposure will become a high dose exposure because metabolism is impaired and she is then exposed to the risks of thrombosis. The process of metabolizing the estrogen could also possibly worsen her liver's ability to metabolize other medications.
- **Hepatic adenoma**. The old high dose pills used to be associated with benign hepatic adenomas, which could sometimes distend, enlarge the liver, and rupture causing bleeding. Recent literature states the low dose pills have not had this problem but any estrogen containing prescription label will contain this warning. If someone has a known diagnosis of hepatic adenoma, estrogen is contraindicated.
- Suspected **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of hormonal products could worsen their prognosis.
- Suspected **pregnancy**, although there is no evidence of teratogenesis in women who inadvertently took low dose oral contraceptives during the first four months of pregnancy.
- Women with **diabetes and microvascular disease** such as retinal or renal damage proven or suspected is an absolute contraindication to estrogen use. Retinal vessel damage is not usually seen till after 10 years of insulin use and is very rare in non-insulin users. Diabetic women on insulin are followed by primary care providers and should have regular eye, renal and lipid evaluations with these

providers. Estrogen and progestin use may change slightly the insulin dose needed but it is safe, will not worsen their diabetes, and is preferable to pregnancy.

- Women with **hypertension**, even if treated, have an increased cardiovascular risk with the use of estrogen. Consider changing to a method with no estrogen, or if unacceptable, the 20 mcg estrogen pill or ring with the **Birth Control Method Specific Informed Consent Form**. If the blood pressure remains elevated or worsens after 3 months, then COC pill or ring use should cease. Estrogen can increase blood pressure and fluid retention. This means hormonal contraceptives can interfere with hypertension medications and treatment.
- In women with **epilepsy**, pills or the ring may be less effective due to **seizure medication** use. This includes carbamazepine, primidone, phenytoin (Dilantin), and phenobarbital. The Family Planning Program will not be prescribing 50 mcg estrogen dose pills because estrogen absorption and metabolism is very different in individual women. The woman on a high dose estrogen pill is exposed to potentially higher thrombotic risks. Estrogen also lowers the seizure threshold in the brain and can increase the number of seizures. The IUD or DMPA injection are the preferred hormonal contraceptive in women on antiepileptic medications. There have been no reports of the use of the ring in women taking these medications and it is a labeled contraindication.
- Use of **rifampin** for tuberculosis increases the metabolism of estrogen and will make the pills and probably the ring less effective. During short-term therapy such as meningitis prophylaxis, continue the ring but use a back-up method also as rifampin use has been associated with many pill failures;
- **Immobility** such as need for a wheelchair, non-weight-bearing long leg cast, major surgery defined as causing immobility for more than two days or a long surgery, greater than two hours, planned, etc., which will predispose to thrombosis. Need to discontinue the ring use 4 weeks prior.
- **Any patient with acute or recent serious illness or chronic serious cardiovascular, vascular, or renal disorders** which may be aggravated by thrombosis or fluid retention such as congestive heart failure, renal dialysis, artificial heart valve for which the client is on anticoagulants, Lupus, Kawasaki disease with prior CAD, and many more conditions. If a patient has a serious medical condition it is often prudent to consult the Family Planning Medical Director prior to prescribing an estrogen containing method because there may indeed be a risk not discussed in the guidelines.
- **Hydatidiform mole or choriocarcinoma** currently being treated, with elevated serum HCG levels, should not have COC pills and perhaps not use the ring since similar hormonal medication until the HCG levels are normal. A large case study of women with choriocarcinoma found that women given COC pills while their HCG levels were elevated were significantly more likely to require chemotherapy than those that did not use exogenous hormones until the HCG level had returned to normal (which would be close to zero).

Precautions

Women with the following may be given a ring prescription if, in the judgment of the clinician, an alternative method of contraception would not be acceptable to the client or would increase the risk of an unwanted pregnancy.

- **Pelvic relaxation or prolapse** such that the ring may be expelled easily. Expulsion was rare in the studies with the ring, with fewer than 2% of women quitting because of ring expulsion, but they

excluded obese women and women with chronic constipation. Hence a woman who frequently strains when toileting may lose the ring in the toilet. The ring can be washed with warm water and if needed a mild soap, and replaced into the vagina.

- **Undiagnosed vaginal bleeding** until diagnosis is established and managed. Although often COC pills or the ring could be used to regulate irregular menses. If the COC pills regulate the menses there is usually no further need for diagnostic tests. A 3 to 6 month trial of COC pills or ring can be a diagnostic maneuver, proving that the history of irregular menses was most likely caused by lack of regular ovulation.
- **Lactation:** The amount and possibly the quality of milk will be lessened with the use of estrogen especially in the first 6 months post partum. If weaning is desired, COC pills or the ring may be used to decrease the flow of milk. If lactation is desired a progestin-only hormonal contraceptive is preferred and can actually increase the amount of milk produced. If lactation is well established and greater than six months, then a change to COC pills is possible but if there are problems, change back to POP.
- **Active gall bladder disease.** Estrogen use can worsen stone formation and dilation of the bile ducts. If they have had their gallbladder removed then there is no risk with COC pill or ring use.
- **Chronic yeast vaginitis.** This may possibly be worsened by estrogen use especially if cyclic with monthly withdrawal bleeding. Estrogen users often have yeast colonization. There is a study that found DMPA use, which reduces estrogen levels, decreased the number of yeast infections.
- **Chronic vaginitis or vaginal pain.** In the studies with the ring approximately 1/3 of the women quitting the ring did so because of complaints relating to the ring including an increase in vaginal discharge. There were no exams to confirm any pathology or comparison to other hormonal contraceptives. Several studies with the NuvaRing™ included colposcopy and cultures and there were no significant changes with ring use so it is highly unlikely the ring harms the vagina. But a woman with chronic problems may have difficulty accepting or tolerating a vaginal delivery system.
- **Spermicides and topical vaginal medications** did not alter the contraceptive steroid release from the ring and thus can be used when using the ring according to the package labeling.
- Use of **oral antibiotics** in particular metronidazole, amoxicillin, ampicillin, and tetracycline, have been associated with case reports of COC pill failure while taking these and other antibiotics. The mechanism for the failure is probably a change in the gut flora so the enterohepatic absorption and circulation of the estrogen and progesterone change resulting in subtherapeutic levels. It is unknown at this time if the ring because it delivers the hormones via the vagina would be unaffected by antibiotic use and at this time it is prudent to give the same advice as given with OCP use. The most conservative advice is to use a back-up method for the duration of antibiotic use (see [OCPs and Antibiotic Use Handout](#)) although the current Contraceptive Technology edition does not think this is necessary with COC pill use, others do suggest one discuss it with the woman and recommend a back up method until 7 days after the antibiotic use is completed. POP users should be told to use a back-up method. If the woman is on chronic, daily low dose antibiotics (like acne suppression with tetracycline or nightly Septra for pyelonephritis prevention) use the **Birth Control Method Specific Informed Consent Form** advising the pill method may not be as effective as in a non-antibiotic user. If no break through bleeding or diarrhea then most likely there are effective hormone levels. Do not begin these chronic antibiotic users on a 20 mcg COC pill since these are usually women being

treated for acne and would benefit from 30 mcg of estrogen and potentially the daily antibiotic could make the steroid levels even lower.

- Use of other chronic medications, consult the OCP chapter as some may compromise hormonal contraceptive efficacy.

History and Consent

The standard medical history is reviewed by the clinician to confirm absence of absolute and relative contraindications. Counseling should be provided to ascertain ability to comply with placing and removing a ring from the vagina. If contraindications do exist then document other methods discussed, patient's decision to not use other methods, and if appropriate sign the **Birth Control Method Specific Informed Consent Form**. If the client has signed this consent form then she needs to sign it every year when she is given a prescription for the ring. Her risk profile may change and there needs to be documentation that she was offered other methods every year and continues to choose the ring.

Examination

Baseline blood pressure, weight, and pregnancy testing (if needed) should be performed prior to prescription. Although there is no increase in the risk of breast cancer with pill use **annual breast exam** should be performed to emphasize the importance of early detection and screening. There is a small possibility that a rare form of cervical cancer, adenocarcinoma, is increased in long term COC pill users due to the estrogen proliferative effect on cervical ectopy or glandular epithelium of the cervix, and for this reason **annual cervical cytology** should be offered. There is an option of delaying the pelvic exam and those guidelines should be consulted. Progestin thickens the cervical mucous and atrophies the endometrium and this can decrease the ascent of bacteria to the upper genital tract, thus one can find asymptomatic chlamydial infections in OCP users. All ring users should be offered STD screening as per the PHSKC STD guidelines.

Prescribing Rings

During the studies with the ring women were given the ring and did their first insertion at home and no additional teaching was done in the clinic and there were no reports of a retained or "lost" ring. However the package insert should be discussed with the client and a sample ring could be used to demonstrate the insertion and removal technique. The blue sample rings cannot be used in the vagina as they have not verified the dye is safe. The ring must be kept refrigerated prior to dispensing because once the rings are at room temperature they need to be used meaning inserted in the vagina by 4 months. For example if on October 1st one dispensed 4 rings, then by February 1st the last ring must be inserted and it is still effective for that cycle. Rings can be stored by the patient in the refrigerator but they do not need to be. A ring stored in the refrigerator can be kept for 2 years if labeling allows. The rings should not be exposed to direct sunlight or to extremes of temperature. Room temperature is defined as 59 to 86 degrees Fahrenheit per the package labeling. Prescription medication can usually only be dispensed by pharmacies. Washington pharmacy code allows dispensing of contraceptives, and only contraceptives, by non-pharmacy persons at Family Planning Clinics. However rings cannot be dispensed unless there is a valid and current prescription. A prescription can only be written or given orally by a provider with prescribing authority.

- **First time ring users** can only get an initial supply of 1 to 3 cycles. A 3 month revisit is mandated to ask about complaints or difficulties with ring use and to measure the weight and the blood pressure.

These are to be recorded by a clinic nurse and any problems evaluated by the clinician. Make sure the client is using the ring correctly. Use the **Female Contraceptive Visit Form** or similar note at visit. She can then be given another 4 months supply and because of the need for refrigeration and quality control clients cannot get an entire year's supply at one time and must return every 3 to 4 months for new rings.

When to begin ring use

Ring use should ordinarily be **started within the first 5 days of the menses**. If the woman is switching from another hormonal method like pills or injections the ring can be placed immediately with no hormone free interval or at least by the end of the pill free week. Some women report the ring can be displaced with use of a tampon and for this reason the first few days of the menses could be avoided if heavy vaginal bleeding is expected. But a first menstrual day start may induce faster and more complete ovarian suppression and is highly recommended if continuous ring use for menstrual suppression is being prescribed.

- Women starting ring **after the 5th day of menses** should use added protection for 7 days. If starting before or by the 5th day of menses then a week of back up for the 1st cycle is recommended by the ring labeling unless the woman has been using a hormonal method properly in the cycle prior.
- Ring use may be started **21 days post partum** in women choosing not to breast feed (estrogen can stop lactation) or on the **day of an abortion** for any pregnancy less than a late second trimester. After 24 or more weeks gestation, do not start estrogen use until three weeks post-delivery or abortion to minimize the risk of increased thrombosis post delivery. By 2 to 3 weeks post partum, 30% of non-breast feeding women will ovulate and could potentially get pregnant.
- **Same Day Start/Restart** may be done if the patient understands and consents. This means the first ring is placed the day of the clinic visit and can even be done there in the clinic with teaching. This may be appropriate in women taking ECP, or who has recently been on pills and missed more than 3 days of pills, or who has had a history of irregular menses and waiting until menses will increase the risk of pregnancy. It may also be appropriate for women whom the provider thinks may benefit from ring use teaching. Documentation of a negative HCG test is required. Consider if the client also needs an EC prescription because regular dose OCPs will not act as an EC. The client must understand the need for a backup method for 2 weeks and that a pregnancy test should be done in 4 weeks, especially if no bleeding. Provide counseling to the client that beginning a hormonal method midcycle can result in increased break-through bleeding and if it is worrisome to the patient, it may be better to wait until the next menses. But in some women, like prior DMPA users, beginning a hormonal method when the client wishes to start is better than waiting for a menses. After 3 months of ring use typically the cycles are regulated and the same day start will have no lasting effect.

How to use the ring

The foil sachet is opened and after washing her hands the woman can place the ring in the vagina. There is no need for a pelvic exam or a fitting exam because the NuvaRing™ is not like a diaphragm. The ring can be placed anywhere in the vagina, "there is no wrong way to put it in". Once in the vagina the ring should not be felt and if the ring is felt the patient can just gently push it deeper into the vagina. Less than 2% of women using the ring in the studies quit using the ring because of expulsions and these were typically with defecation or bearing down and may have been only a single event. The ring is then left in place for 21 days. In the event the ring comes out it should be immediately replaced. If necessary the

ring can be rinsed off with warm (never hot or freezing) water and if necessary a mild soap. If the ring was left out for 3 or more hours then the labeling instructs the woman to use a back up method for 7 days. If the extended ring removal was in the third week of the ring use it is advised she skip the ring free week and after the 21st day just insert a new ring without a ring free week. After use of the ring, it is to be placed into the same or perhaps the next, foil sachet, sealed and discarded in the trash and never the toilet.

- Each month the client will need to remember to change the ring. One way might be to have her always take out on the 25th of the month and put a new one in on the 1st of the next month. This means the period week is of variable length but it is easy to remember and it is never more than 7 days so coverage is assured.
- Extended or continuous CVR use to suppress withdrawal bleeding. A woman could choose to do this with the CVR. The levels of hormone stay high enough to block ovulation up to 5 weeks (35 days) of use, but it is best to go no longer than 1 month of use per ring. Insert a new ring on a set day like the 1st of each month to take out old ring and insert a new ring. If the woman notices a lot of spotting at the end of each month, changing to a new ring sooner (by 4 weeks) may help. It is likely just as with continuous pill use irregular bleeding will be common in the first 6 months and less of a problem with long term use.

Product Brochure

The manufacturer's patient product labeling is to be given to the client each time rings are dispensed. Clients can also find information at www.nuvaring.com or 1-877-nuvaring. The company will be making available a monthly timer to help women remember to take out the ring on day 21 and reinsert a new ring on day 28.

Possible Side Effects

- **Nausea.** The nausea is not the result of a local effect on the stomach but because the estrogen is working on the brain to cause nausea. For this reason even women using the ring may experience nausea.
- **Weight Gain.** In studies of large numbers of women OCPs did not significantly increase the weight of the population however individual women may respond differently to hormone use. Weight gain is usually from increased food consumption and decreased activity. In the 2400 women using the ring in the clinical trials the weight gain was similar to that as measured in pill users, a little under a pound after one year.
- **Breakthrough Bleeding (BTB) or Spotting.** BTB is when the woman reports having bleeding between the ring days or scheduled withdrawal bleeding. BTB is defined as enough bleeding to need a hygiene product like pads or tampons and spotting is when no protection was needed. In the studies with the ring compared to the pill there was less BTB with the ring, but 1/3 of women were still bleeding at the end of the ring free week so important to tell patients to put in a new ring, even if bleeding, after 7 days of no ring.

First 6 months of ring use:

- **Reassure client** this is very common when first beginning hormonal methods and is often because the uterine lining is shrinking and shedding under hormonal influence.
- Use the [Menstrual Calendar Reminder Card](#) to help patients track their bleeding and spotting.
- Be certain that the ring is being **used as scheduled** as a drop in the hormonal levels can worsen BTB and spotting. It is possible a shorter ring free interval or no ring free interval may help but totally unproven. What is known is with time the amount of BTB will decrease.
- **Rule out other causes** of bleeding as appropriate by history and exam such as pregnancy, polyps, cervicitis, or other medication use.
- **Ibuprofen**, 400 to 800 mg three times daily or Naprosyn 500 mg twice a day beginning with menses, can reduce the amount of menstrual flow and the frequency of BTB or spotting. Menses or menstrual withdrawal bleeding is triggered by a drop in progesterone, which results in prostaglandin production. These chemicals then shed the endometrium by vessel spasm hence the pain and cramps.
- **Recent history of DMPA:** Injections could alter the ratio of hormone levels since DMPA is not completely cleared for 6 months after use. Because of DMPA's progestin effect on the endometrium to cause atrophy increasing estrogen may suppress BTB or spotting. The ring releases a very potent progestin, but only a low level of estrogen. Switching to a pill with a higher estrogen dose may be tried. Use of the ring with concomitant combination birth control pills is contraindicated. There are no published studies on the best formulation to transition women from DMPA to ring use. In a randomized study of DMPA users, supplemental estrogen did not help BTB. This has not been studied in OCP or ring users, but it is unlikely to help except acutely and since estrogen causes proliferation it could be counter productive with increased bleeding when the supplemental estrogen is stopped. Switching to a COC pill with an increased EE dose for ongoing use might be considered.
- **Alcohol use** can also change the metabolism of estrogen so that the estrogen is metabolized slower giving higher estrogen levels. Using alcohol daily, binge drinking or stopping alcohol consumption could trigger some transitory BTB or spotting.
- **Tobacco use** induces metabolism of estrogen making some smokers more vulnerable to breakthrough bleeding and spotting.

After 6 months of ring use:

- The endometrium has atrophied and the most likely etiology is noncompliant ring use. For this reason **pregnancy testing** may be advised if the woman presents with bleeding complaints.
- If unexplained breakthrough bleeding occurs in women established on the ring, do an **infection check** and evaluate for other sources of bleeding before pill change. If no etiology is found and the BTB or spotting persists after two cycles, referral is indicated to gynecology clinic to evaluate for uterine or ovarian pathology.

- **Breast Tenderness.** This will usually disappear within three cycles. If not, lower doses of estrogen may help. Instruct in obtaining and using proper bra. Discuss the possible role of caffeine. Some women may benefit from vitamin E 400 IU daily.
- **Headache.** Allow two to three cycles for adjustment and recommend aspirin, ibuprofen or acetaminophen. Use the **Headache Diary**. Consider discontinuing the ring if migraine headaches worsen with continued use. If severe, persistent, or vascular symptoms like blindness or numbness develop, stop ring use and refer to a neurologist and to an emergency room if acute. Estrogen withdrawal headaches can decrease with cycle elimination and taking a 20 mcg OCP or using the ring continuously without a break for menses may be considered.
- **Watery vaginal discharge.** If excessive vaginal discharge is still present after two to three cycles, perform a pelvic exam and rule out vaginitis or cervicitis. If it is a physiologic discharge there is no treatment and ring use might be discontinued with a follow up visit a month later to see if it has resolved.
- **Oligomenorrhea and Amenorrhea.** This is uncommon with cyclic ring use (less than 5% of users over one year). Menstrual changes are not harmful and the client needs only reassurance. If the woman strongly desires to have periods, a higher estrogen product like a pill may be tried. If there is any reason to suspect pregnancy (forgotten pills, symptoms, suspicious pelvic exam, etc.) or two missed menses successively, then a pregnancy test should be done as appropriate.
- **Depression and Irritability.** A low sodium diet may help if premenstrual mood changes. Hepatic metabolism of estrogen can deplete vitamin B6 (pyridoxine) so a 50 to 100 mg daily dose can be tried to see if mood improves. There is no evidence the ring has no effect on the B6 system and it is possible the lower dose of estrogen could also affect mood. If mood changes appear to be cyclic, then extended or continuous cycles could be tried.
- **Increased Blood Pressure.** Repeat measurement after a brief rest in the clinic. If the increase is sustained, consult and use the Family Planning Hypertension guidelines. If diastolic continues to be 90 mm or greater then the client can use the ring only after signing the **Birth Control Method Specific Informed Consent Form**, and repeat visit in 3 months with discontinuation if still hypertensive.
- **Acne and oily skin.** Estrogen causes an increase in hepatic production of Serum Hormone Binding Globulin (SHBG). SHBG then binds to free testosterone and androgens effectively reducing the free, which are the active, androgenic hormones. This is why all COC pills can reduce acne and hirsutism. Ortho Tricyclen, a Norgestimate triphasic, is a COC pill that has package labeling as a treatment for acne. A study compared this pill to placebo and not to another COC pill. Other COC pills also reduce acne. Probably the best pill to reduce acne would be a pill with 35 mcg of EE and low dose of a weak nonandrogenic progestin like NET (Ovcon 35). The ring has not been proven to reduce acne although acne was a rare complaint in the studies and it is unlikely to be different than the COC pill since SHBG levels were actually higher in the ring users compared to the pill users.
- **Decreased Libido.** This may be related to decreased circulating androgens. Vaginal dryness may be managed with lubricants or increased estrogen dose. A review of sexual arousal and taking a sexual history is also important.

- **Chloasma** (melasma). Hyperpigmentation areas on the face are a great cosmetic concern. Occurrence is related to sun exposure, family history, and pregnancy, and can be due to estrogen levels especially pregnancy and COC pill use. Pigmentation can be reduced by avoiding all exposure to the sun. Use of a high potency sunscreen especially on the affected areas may benefit. Bleaching agents such as hydroquinone, or tretinoin in topical creams are frequently helpful. DO NOT prescribe these, only refer. If a woman develops chloasma during pregnancy or with COC pill or ring use she is at risk to develop it with repeated estrogen use or pregnancy. Sometimes the skin changes are permanent even after discontinuation so women may choose to discontinue use of rings or COC pills to prevent further discoloration.